



## Clinical trial results:

### Maintenance of Response After Open-Label Treatment with Atomoxetine Hydrochloride in Adult Outpatients with Attention-Deficit/Hyperactivity Disorder (ADHD): A Placebo-Controlled, Randomized Withdrawal Study

#### Summary

EudraCT number	2007-007672-41
Trial protocol	GB NL DE ES FR PT SE AT FI BE DK IT
Global end of trial date	02 October 2013

#### Results information

Result version number	v1 (current)
This version publication date	04 July 2016
First version publication date	02 August 2015

#### Trial information

##### Trial identification

Sponsor protocol code	B4Z-MC-LYDO
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##### Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00700427
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Alias: B4Z-MC-LYDO, Trial Number: 9655

Notes:

##### Sponsors

Sponsor organisation name	Eli Lilly and Company
Sponsor organisation address	Lilly Corporate Center, Indianapolis, IN, United States, 46285
Public contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-CTLilly,
Scientific contact	Available Mon - Fri 9 AM - 5 PM EST, Eli Lilly and Company, 1 877-285-4559,

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	02 October 2013
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	02 October 2013
Was the trial ended prematurely?	No

Notes:

## General information about the trial

Main objective of the trial:

The primary objective of Study LYDO is to test the hypothesis that atomoxetine is superior to placebo in maintaining a satisfactory response at the end of double-blind treatment in adult outpatients with ADHD who show a satisfactory response to acute atomoxetine treatment, as measured by the proportion of patients who meet predefined response criteria.

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonisation (ICH) Good Clinical Practice, and the principles of the Declaration of Helsinki, in addition to following the laws and regulations of the country or countries in which a study is conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 June 2008
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

## Population of trial subjects

### Subjects enrolled per country

Country: Number of subjects enrolled	Netherlands: 71
Country: Number of subjects enrolled	Portugal: 3
Country: Number of subjects enrolled	Spain: 153
Country: Number of subjects enrolled	Sweden: 112
Country: Number of subjects enrolled	United Kingdom: 27
Country: Number of subjects enrolled	Austria: 109
Country: Number of subjects enrolled	Belgium: 137
Country: Number of subjects enrolled	Denmark: 15
Country: Number of subjects enrolled	Finland: 52
Country: Number of subjects enrolled	France: 65
Country: Number of subjects enrolled	Germany: 434
Country: Number of subjects enrolled	Italy: 32
Country: Number of subjects enrolled	Russian Federation: 6
Country: Number of subjects enrolled	Switzerland: 7
Country: Number of subjects enrolled	United States: 602
Country: Number of subjects enrolled	Mexico: 53
Country: Number of subjects enrolled	Argentina: 27
Country: Number of subjects enrolled	Canada: 60
Country: Number of subjects enrolled	Puerto Rico: 52

Worldwide total number of subjects	2017
EEA total number of subjects	1210

Notes:

<b>Subjects enrolled per age group</b>	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	2017
From 65 to 84 years	0
85 years and over	0

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

The study consisted of 4 treatment periods: 12 weeks open-label, acute-treatment (trx) phase (Study Period 2), 12 weeks double-blind maintenance phase of Study Period 3 (Study Period 3A), 25 weeks double-blind randomized withdrawal phase of Study Period 3 (Study Period 3B) and an Open-Label Extension Period (Study Period 4) lasting up to 2.3 year

### Period 1

Period 1 title	Study Period 2 (Open-Label Acute Trx)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

### Arms

<b>Arm title</b>	Atomoxetine (Study Period 2)
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Arm description:

40-100 milligrams/day (mg/day) atomoxetine orally, once daily or twice daily for 12 weeks during open-label, acute-treatment phase (Study Period 2).

Arm type	Experimental
Investigational medicinal product name	atomoxetine hydrochloride
Investigational medicinal product code	
Other name	Strattera, LY139603, Atomoxetine
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Starting dose 40 milligrams/day (mg/day) and target dose 80-100 mg/day atomoxetine orally, once daily or twice daily for 12 weeks during open-label, acute-treatment phase (Study Period 2).

<b>Number of subjects in period 1</b>	Atomoxetine (Study Period 2)
Started	2017
Received at Least One Dose of Study Drug	2011
Completed	1006
Not completed	1011
Consent withdrawn by subject	164
Physician decision	8
Clinical Relapse	7
Adverse Event	298
Protocol Interim Criteria Not Met	161
Protocol Violation	173
Lost to follow-up	108

Entry Criteria Not Met	2
Lack of efficacy	90

## Period 2

Period 2 title	Study Period 3A (Blinded Maintenance)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

## Arms

<b>Arm title</b>	Atomoxetine (Study Period 3A)
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Arm description:

80-100 milligrams/day (mg/day) atomoxetine orally, once daily or twice daily for 12 weeks during double-blind maintenance phase (Study Period 3A).

Arm type	Experimental
Investigational medicinal product name	atomoxetine hydrochloride
Investigational medicinal product code	
Other name	Strattera, LY139603, Atomoxetine
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Starting dose 40 milligrams/day (mg/day) and target dose 80-100 mg/day atomoxetine orally, once daily or twice daily for 12 weeks during double-blind randomized withdrawal phase (Study Period 3).

<b>Number of subjects in period 2<sup>[1]</sup></b>	Atomoxetine (Study Period 3A)
Started	1005
Completed	524
Not completed	481
Consent withdrawn by subject	81
Physician decision	2
Missing - Not Otherwise Defined	5
Clinical Relapse	49
Adverse Event	50
Protocol Interim Criteria Not Met	162
Sponsor Decision	3
Protocol Violation	56

Lost to follow-up	41
Lack of efficacy	32

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: One participant was mistakenly recorded as completed. The reason for discontinuation is unknown.

**Period 3**

Period 3 title	Study Period 3B (Randomized Withdrawal)
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

**Arms**

Are arms mutually exclusive?	Yes
<b>Arm title</b>	Atomoxetine (Study Period 3B)

Arm description:

80-100 mg/day atomoxetine orally, once daily or twice daily for 25 weeks during double-blind randomized withdrawal phase of Study Period 3 (Study Period 3B).

Arm type	Experimental
Investigational medicinal product name	atomoxetine hydrochloride
Investigational medicinal product code	
Other name	Strattera, LY139603, Atomoxetine
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

80-100 mg/day atomoxetine orally, once daily or twice daily for 25 weeks during double-blind randomized withdrawal phase of Study Period 3 (Study Period 3B).

<b>Arm title</b>	Placebo (Study Period 3B)
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Arm description:

Placebo orally, once daily or twice daily for 25 weeks during double-blind randomized withdrawal phase of Study Period 3 (Study Period 3B).

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

Dosage and administration details:

Placebo orally, once daily or twice daily for 25 weeks during double-blind randomized withdrawal phase of Study Period 3 (Study Period 3B).

<b>Number of subjects in period 3</b>	Atomoxetine (Study Period 3B)	Placebo (Study Period 3B)
Started	266	258
Completed	184	165
Not completed	82	93
Adverse event, serious fatal	1	-
Consent withdrawn by subject	25	34
Missing - Not Otherwise Defined	1	1
Physician decision	2	-
Clinical Relapse	-	3
Adverse Event	8	5
Protocol Interim Criteria Not Met	-	5
Protocol Violation	23	25
Lost to follow-up	19	9
Lack of efficacy	3	11

#### Period 4

Period 4 title	Study Period 4 (Open-Label Extension)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

#### Arms

<b>Arm title</b>	Atomoxetine (Study Period 4)
Arm description: -	
Arm type	Experimental
Investigational medicinal product name	atomoxetine hydrochloride
Investigational medicinal product code	
Other name	Strattera, LY139603, Atomoxetine
Pharmaceutical forms	Capsule
Routes of administration	Oral use

#### Dosage and administration details:

Participants who received either atomoxetine or placebo and completed the last visit of Study Period 3 who were in countries where the adult ADHD indication for atomoxetine was not approved were allowed to participate in Study Period 4 (Open-label Extension). Participants received 40 mg/day atomoxetine orally for at least 7 days after which it was increased to 80-100 mg/day atomoxetine orally for up to 2.3 years.

<b>Number of subjects in period 4</b>	<b>Atomoxetine (Study Period 4)</b>
Started	349
Completed	96
Not completed	253
Adverse event, serious fatal	1
Consent withdrawn by subject	38
Physician decision	2
Clinical Relapse	1
Adverse Event	16
Only available in Europe, subject not in Europe	169
Sponsor Decision	2
Protocol Violation	12
Lost to follow-up	11
Lack of efficacy	1



## Baseline characteristics

### Reporting groups

Reporting group title	Study Period 2 (Open-Label Acute Trx)
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Reporting group description: -

Reporting group values	Study Period 2 (Open-Label Acute Trx)	Total	
Number of subjects	2017	2017	
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	33.15 ± 9.09	-	
Gender categorical Units: Subjects			
Female	833	833	
Male	1184	1184	
Race/Ethnicity Units: Subjects			
Caucasian	1765	1765	
African	56	56	
Hispanic	159	159	
Native American	6	6	
East Asian	14	14	
West Asian	15	15	
Missing	2	2	

## End points

### End points reporting groups

Reporting group title	Atomoxetine (Study Period 2)
Reporting group description: 40-100 milligrams/day (mg/day) atomoxetine orally, once daily or twice daily for 12 weeks during open-label, acute-treatment phase (Study Period 2).	
Reporting group title	Atomoxetine (Study Period 3A)
Reporting group description: 80-100 milligrams/day (mg/day) atomoxetine orally, once daily or twice daily for 12 weeks during double-blind maintenance phase (Study Period 3A).	
Reporting group title	Atomoxetine (Study Period 3B)
Reporting group description: 80-100 mg/day atomoxetine orally, once daily or twice daily for 25 weeks during double-blind randomized withdrawal phase of Study Period 3 (Study Period 3B).	
Reporting group title	Placebo (Study Period 3B)
Reporting group description: Placebo orally, once daily or twice daily for 25 weeks during double-blind randomized withdrawal phase of Study Period 3 (Study Period 3B).	
Reporting group title	Atomoxetine (Study Period 4)
Reporting group description: -	
Subject analysis set title	Outcome Measure 1 Atomoxetine
Subject analysis set type	Intention-to-treat
Subject analysis set description: Primary outcome measure analysis was conducted using all randomized participants in the Double-Blind Maintenance/Randomized Withdrawal Period (Study Period 3B).	
Subject analysis set title	Outcome Measure 1 Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: Primary outcome measure analysis was conducted using all randomized participants in the Double-Blind Maintenance/Randomized Withdrawal Period (Study Period 3B).	
Subject analysis set title	Outcome Measure 2 Atomoxetine
Subject analysis set type	Intention-to-treat
Subject analysis set description: Analyses were conducted using all randomized participants in the Double-Blind Period (Study Period 3B).	
Subject analysis set title	Outcome Measure 2 Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: Analyses were conducted using all randomized participants in the Double-Blind Period (Study Period 3B).	
Subject analysis set title	Outcome Measure 3 Atomoxetine
Subject analysis set type	Intention-to-treat
Subject analysis set description: All randomized participants with a baseline and at least 1 post-baseline AAQoL score were included in the analysis.	
Subject analysis set title	Outcome Measure 3 Placebo
Subject analysis set type	Intention-to-treat
Subject analysis set description: All randomized participants with a baseline and at least 1 post-baseline AAQoL score were included in the analysis.	
Subject analysis set title	Outcome Measure 4 Atomoxetine
Subject analysis set type	Intention-to-treat
Subject analysis set description: Participants with a non-missing baseline and at least 1 post-baseline CAARS-O:SV result within each	

group, Last Observation Carried Forward (LOCF) were included in the analysis.

Subject analysis set title	Outcome Measure 4 Placebo
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with a non-missing baseline and at least 1 post-baseline CAARS-O:SV result within each group, Last Observation Carried Forward (LOCF) were included in the analysis.

Subject analysis set title	Outcome Measure 5 Atomoxetine
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with a non-missing baseline and at least 1 post-baseline CAARS-S:SV result within each treatment group, Last Observation Carried Forward (LOCF).

Subject analysis set title	Outcome Measure 5 Placebo
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with a non-missing baseline and at least 1 post-baseline CAARS-S:SV result within each treatment group, Last Observation Carried Forward (LOCF).

Subject analysis set title	Outcome Measure 6 Atomoxetine
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with a non-missing baseline and at least 1 post-baseline BRIEF-A:Self Report result within each group, Last Observation Carried Forward (LOCF) were included in the analysis.

Subject analysis set title	Outcome Measure 6 Placebo
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with a non-missing baseline and at least 1 post-baseline BRIEF-A:Self Report result within each group, Last Observation Carried Forward (LOCF) were included in the analysis.

Subject analysis set title	Outcome Measure 7 Atomoxetine
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with a non-missing baseline and at least 1 post-baseline BRIEF-A:Informant result within each group, Last Observation Carried Forward (LOCF) were included in the analysis.

Subject analysis set title	Outcome Measure 7 Placebo
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with a non-missing baseline and at least 1 post-baseline BRIEF-A:Informant result within each group, Last Observation Carried Forward (LOCF) were included in the analysis.

Subject analysis set title	Outcome Measure 8 Atomoxetine
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with a non-missing baseline and at least 1 post-baseline EQ-5D Index Score or VAS score within each group, Last Observation Carried Forward (LOCF) were included in the analysis.

Subject analysis set title	Outcome Measure 8 Placebo
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Participants with a non-missing baseline and at least 1 post-baseline EQ-5D Index Score or VAS score within each group, Last Observation Carried Forward (LOCF) were included in the analysis.

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### **Primary: Percentage of Participants Who Maintain a Satisfactory Response During the Double-Blind Maintenance/Randomized Withdrawal Period**

End point title	Percentage of Participants Who Maintain a Satisfactory Response During the Double-Blind Maintenance/Randomized Withdrawal Period
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End point description:

Conners' Adult ADHD Rating Scale-Investigator Rated:Screening Version (CAARS-Inv:SV); 30-item scale (3 subscales): inattention, hyperactivity/impulsivity (9 items each), ADHD Index (12 items). Each item is scored 0 (not at all/never) to 3 (very much/very frequently). Total ADHD symptoms score (SS)

=inattention+hyperactivity/impulsivity (range:0-54). Higher score=more impairment. Clinical Global Impressions-ADHD-Severity (CGI-ADHD-S) measures participant's overall severity of ADHD symptoms and scores range from 1 (normal, not at all ill) to 7 (among the most extremely ill participants). Maintenance of response during the randomized withdrawal phase was a reduction of  $\geq 30\%$  in the baseline CAARS-Inv:SV Total ADHD SS and a CGI-ADHD-S score  $\leq 3$ . Participants had to continuously meet the response criteria, except for 1 excursion after assessment at Week 24 through Week 37 and 1 other excursion after assessment at Week 37 through Week 49. Excursions were not permitted at 2 consecutive visits.

End point type	Primary
End point timeframe:	
Baseline (Week 24) up to Week 49	

End point values	Outcome Measure 1 Atomoxetine	Outcome Measure 1 Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	266	258		
Units: percentage of responders	64	50		

### Statistical analyses

Statistical analysis title	Statistical Analysis 1 for Outcome Measure 1
Comparison groups	Outcome Measure 1 Atomoxetine v Outcome Measure 1 Placebo
Number of subjects included in analysis	524
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Fisher exact

### Secondary: Number of Days Until Relapse

End point title	Number of Days Until Relapse
End point description:	
Relapse was defined as 2 consecutive visits with a CGI-ADHD-S score $\geq 4$ points and a return to $\geq 80\%$ of participant's baseline (Visit 2) CAARS-Inv:SV Total ADHD Symptom Score (SS). If the participant showed evidence of a return of symptoms at a single visit that met severity criteria described above, and because of worsening symptoms, was unwilling to remain in the study or did not return for a second visit, the participant was also considered to have relapsed. CAARS-Inv:SV is a 30-item scale (3 subscales): Inattention, Hyperactivity/Impulsivity (9 items each), ADHD Index (12 items). Each item is scored 0 (0=not at all/never) to 3 (very much/very frequently). Total ADHD SS=inattention+hyperactivity/impulsivity (range: 0-54). Higher score=more impairment. CGI-ADHD-S measures participant's overall severity of ADHD symptoms and scores range from 1 (normal, not at all ill) to 7 (among the most extremely ill participants). Due to limitations, values listed as 99999 represent Not Applicable	
End point type	Secondary
End point timeframe:	
Baseline (Week 24) up to Week 49	

End point values	Outcome Measure 2 Atomoxetine	Outcome Measure 2 Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	266 <sup>[1]</sup>	258 <sup>[2]</sup>		
Units: days				
arithmetic mean (standard deviation)	999999 (± 999999)	999999 (± 999999)		

Notes:

[1] - Mean & standard deviation couldn't be reliably estimated because of low numbers of relapsed subjects

[2] - Mean & standard deviation couldn't be reliably estimated because of low numbers of relapsed subjects

## Statistical analyses

No statistical analyses for this end point

## Secondary: Change From Baseline in the Adult Attention-Deficit/Hyperactivity Disorder (ADHD) Quality of Life (AAQoL) Scale From Week 24 to Week 49

End point title	Change From Baseline in the Adult Attention-Deficit/Hyperactivity Disorder (ADHD) Quality of Life (AAQoL) Scale From Week 24 to Week 49
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End point description:

The AAQoL is a self-reported, 29-item scale assessing functional impairments in adults with ADHD. Each item is rated on a 5-point Likert scale; range: 1 (Not at all/ Never) to 5 (Extremely/Very Often). 5-domains of scale include: work functioning, family relationships, social functioning, activities of daily living (driving, managing finances), and psychological adaptation (life satisfaction, self-esteem). These scores are transformed to a 0-100 point scale (1=0; 2=25; 3=50; 4=75; 5=100), and then the item scores are summed and divided by item count to generate overall scores. The overall scores have the same total range of scores of 0-100, with higher scores indicating better quality of life. Least Squares (LS) Mean values were adjusted for baseline AAQoL score and Investigator/site.

End point type	Secondary
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End point timeframe:

Baseline (Week 24), Week 49

End point values	Outcome Measure 3 Atomoxetine	Outcome Measure 3 Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	198	180		
Units: units on a scale				
least squares mean (standard error)	0.4 (± 1.12)	-4 (± 1.1)		

## Statistical analyses

Statistical analysis title	Statistical Analysis 1 for Outcome Measure 3
Comparison groups	Outcome Measure 3 Atomoxetine v Outcome Measure 3

	Placebo
Number of subjects included in analysis	378
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002
Method	ANCOVA

## Secondary: Change From Baseline in Conner's Adult Attention-Deficit/Hyperactivity Disorder (ADHD) Rating Scale (Observer Rated [CAARS-O:SV]) Total ADHD Symptom Score From Week 24 to Week 49

End point title	Change From Baseline in Conner's Adult Attention-Deficit/Hyperactivity Disorder (ADHD) Rating Scale (Observer Rated [CAARS-O:SV]) Total ADHD Symptom Score From Week 24 to Week 49
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### End point description:

The CAARS-O:SV is a 30-item observer (typically a significant other or close friend) completed scale containing 3 subscales: inattention (9 items), hyperactivity/impulsivity (9 items), and ADHD Index (12 items). Each item is scored 0-3 (0=not at all/never; 1=just a little/once in a while; 2=pretty much/often; 3=very much/very frequently). Inattention and hyperactivity subscales range from 0-27; ADHD index subscale range is 0-36 with higher scores indicating more impaired participants. Total ADHD symptoms score=sum of the inattention and hyperactivity/impulsivity subscales, ranging from 0-54, with higher scores indicating more impaired participants. Least Squares (LS) Mean values adjusted for treatment, pooled Investigator, and baseline.

End point type	Secondary
End point timeframe:	
Baseline (Week 24), Week 49	

End point values	Outcome Measure 4 Atomoxetine	Outcome Measure 4 Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	165	153		
Units: units on a scale				
least squares mean (standard error)				
ADHD Imputed (Attributed) Index Score (N=164, 153)	-2.6 (± 0.56)	-0.1 (± 0.57)		
Hyperactivity/Impulsivity Subscale Imputed Score	-1.9 (± 0.44)	-0.1 (± 0.44)		
Inattention Subscale Imputed Score	-1.6 (± 0.46)	-0.1 (± 0.46)		
Total ADHD Symptom Imputed Score	-3.5 (± 0.83)	-0.4 (± 0.83)		

## Statistical analyses

Statistical analysis title	Statistical Analysis 1 for Outcome Measure 4
Comparison groups	Outcome Measure 4 Atomoxetine v Outcome Measure 4 Placebo

Number of subjects included in analysis	318
Analysis specification	Pre-specified
Analysis type	superiority <sup>[3]</sup>
P-value	< 0.001
Method	ANCOVA

Notes:

[3] - P-value for ADHD Imputed (Attributed) Index Score.

<b>Statistical analysis title</b>	Statistical Analysis 2 for Outcome Measure 4
Comparison groups	Outcome Measure 4 Atomoxetine v Outcome Measure 4 Placebo
Number of subjects included in analysis	318
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.002 <sup>[4]</sup>
Method	ANCOVA

Notes:

[4] - P-value for Hyperactivity/Impulsivity Subscale Imputed Score.

<b>Statistical analysis title</b>	Statistical Analysis 3 for Outcome Measure 4
Comparison groups	Outcome Measure 4 Atomoxetine v Outcome Measure 4 Placebo
Number of subjects included in analysis	318
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.009 <sup>[5]</sup>
Method	ANCOVA

Notes:

[5] - P-value for Inattention Subscale Imputed Score.

<b>Statistical analysis title</b>	Statistical Analysis 4 for Outcome Measure 4
Comparison groups	Outcome Measure 4 Atomoxetine v Outcome Measure 4 Placebo
Number of subjects included in analysis	318
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.003 <sup>[6]</sup>
Method	ANCOVA

Notes:

[6] - P-value for Total ADHD Symptom Imputed Score.

### **Secondary: Change From Baseline in Conner's Adult ADHD Rating Scale-Self Rated (CARRS-S:SV) Total ADHD Symptom Score From Week 24 to Week 49**

End point title	Change From Baseline in Conner's Adult ADHD Rating Scale-Self Rated (CARRS-S:SV) Total ADHD Symptom Score From Week 24 to Week 49
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End point description:

CAARS-S:SV is a 30-item participant completed scale containing 3 subscales: inattention (9 items), hyperactivity/impulsivity (9 items), ADHD Index (12 items). 0-3 (0=not at all/never; 1=just a little/once in a while; 2=pretty much/often; 3=very much/very frequently). Inattention and hyperactivity subscales range from 0-27; ADHD index subscale range is 0-36 with higher scores indicating more impaired participants. Total ADHD symptoms score=sum of the inattention and hyperactivity/impulsivity

subscales; range: 0-54 with higher scores indicating more impaired participants. Least Squares (LS) Mean values adjusted for treatment, pooled Investigator, and baseline.

End point type	Secondary
End point timeframe:	
Baseline (Week 24), Week 49	

End point values	Outcome Measure 5 Atomoxetine	Outcome Measure 5 Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	193	178		
Units: units on a scale				
least squares mean (standard error)				
ADHD Symptom Imputed Index Score	-1.2 (± 0.44)	0.9 (± 0.43)		
Hyperactivity-Impulsivity Subscale Imputed Score	-0.9 (± 0.33)	0.5 (± 0.32)		
Inattention Subscale Imputed Score	-0.7 (± 0.38)	1.2 (± 0.37)		
Total ADHD Symptom Imputed Score	-1.6 (± 0.65)	1.7 (± 0.64)		

## Statistical analyses

<b>Statistical analysis title</b>	Statistical Analysis 1 for Outcome Measure 5
Comparison groups	Outcome Measure 5 Atomoxetine v Outcome Measure 5 Placebo
Number of subjects included in analysis	371
Analysis specification	Pre-specified
Analysis type	superiority <sup>[7]</sup>
P-value	< 0.001
Method	ANCOVA

Notes:

[7] - P-value for ADHD Imputed (Attributed) Index Score.

<b>Statistical analysis title</b>	Statistical Analysis 2 for Outcome Measure 5
Comparison groups	Outcome Measure 5 Atomoxetine v Outcome Measure 5 Placebo
Number of subjects included in analysis	371
Analysis specification	Pre-specified
Analysis type	superiority <sup>[8]</sup>
P-value	< 0.001
Method	ANCOVA

Notes:

[8] - P-value for Hyperactivity/Impulsivity Subscale Imputed Score.

<b>Statistical analysis title</b>	Statistical Analysis 3 for Outcome Measure 5
Comparison groups	Outcome Measure 5 Atomoxetine v Outcome Measure 5 Placebo



Number of subjects included in analysis	371
Analysis specification	Pre-specified
Analysis type	superiority <sup>[9]</sup>
P-value	< 0.001
Method	ANCOVA

Notes:

[9] - P-value for Inattention Subscale Imputed Score.

<b>Statistical analysis title</b>	Statistical Analysis 4 for Outcome Measure 5
Comparison groups	Outcome Measure 5 Placebo v Outcome Measure 5 Atomoxetine
Number of subjects included in analysis	371
Analysis specification	Pre-specified
Analysis type	superiority <sup>[10]</sup>
P-value	< 0.001
Method	ANCOVA

Notes:

[10] - P-value for Total ADHD Symptom Imputed Score.

### **Secondary: Change From Baseline in the Behavior Rating Inventory of Executive Function-Adult Version: Self Report (BRIEF-A:Self Report) Global Executive Composite (GEC) Index Score From Week 24 to Week 49**

End point title	Change From Baseline in the Behavior Rating Inventory of Executive Function-Adult Version: Self Report (BRIEF-A:Self Report) Global Executive Composite (GEC) Index Score From Week 24 to Week 49
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End point description:

The BRIEF-A:Self Report is a 75-item self-reported measure captures adults' views of their own executive functions/self-regulation in their everyday environment. Items include: Inhibit, Shift, Emotional Control, Self Monitor, Initiate, Working Memory, Plan/Organize, Task Monitor, and Organization of Materials. Behavior is rated on a 3-point scale: 1 (behavior is never observed) to 3 (behavior is often observed). GEC Index Score is a subscore of the 75-item BRIEF-A score, reflects overall functioning and was calculated based on 70 items. Total scores range: 70-210. Lower scores = less perceived impairment. Least Squares (LS) Mean values were adjusted for treatment, pooled Investigator, and baseline.

End point type	Secondary
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End point timeframe:

Baseline (Week 24), Week 49

<b>End point values</b>	Outcome Measure 6 Atomoxetine	Outcome Measure 6 Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	187	173		
Units: units on a scale				
least squares mean (standard error)	-5.7 (± 1.88)	0.9 (± 1.81)		

## **Statistical analyses**

<b>Statistical analysis title</b>	Statistical Analysis 1 for Outcome Measure 6
Comparison groups	Outcome Measure 6 Atomoxetine v Outcome Measure 6 Placebo
Number of subjects included in analysis	360
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	ANCOVA

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**Secondary: Change From Baseline in the Behavior Rating Inventory of Executive Function-Adult Version:Informant Report (BRIEF-A:Informant) Global Executive Composite (GEC) Index Score From Week 24 to Week 49**

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End point title	Change From Baseline in the Behavior Rating Inventory of Executive Function-Adult Version:Informant Report (BRIEF-A:Informant) Global Executive Composite (GEC) Index Score From Week 24 to Week 49
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End point description:

BRIEF-A:Informant is a 75-item third-party observer's view of the participants' executive functions/self-regulation in their everyday environment. Items include: Inhibit, Shift, Emotional Control, Self Monitor, Initiate, Working Memory, Plan/Organize, Task Monitor, and Organization of Materials. Behavior is rated on a 3-point scale: 1 (behavior is never observed) to 3 (behavior is often observed). GEC Index Score is a subscore of the 75-item BRIEF-A score, reflects overall functioning and was calculated based on 70 items. Total scores range: 70-210. Lower scores = less perceived impairment. Least Squares (LS) Mean values were adjusted for treatment, pooled Investigator, and baseline.

End point type	Secondary
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End point timeframe:

Baseline (Week 24), Week 49

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<b>End point values</b>	Outcome Measure 7 Atomoxetine	Outcome Measure 7 Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	154	147		
Units: units on a scale				
least squares mean (standard error)	-8.4 (± 2.16)	-0.6 (± 2.17)		

**Statistical analyses**

<b>Statistical analysis title</b>	Statistical Analysis 1 for Outcome Measure 7
Comparison groups	Outcome Measure 7 Atomoxetine v Outcome Measure 7 Placebo
Number of subjects included in analysis	301
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.006
Method	ANCOVA

## Secondary: Change From Baseline in European Quality of Life (EuroQoL) Questionnaire-5 Dimensions (EQ-5D) Index Score From Week 24 to Week 49

End point title	Change From Baseline in European Quality of Life (EuroQoL) Questionnaire-5 Dimensions (EQ-5D) Index Score From Week 24 to Week 49
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End point description:

The EQ-5D is a Self-reported, 5-item scale to assess health utility (mobility, self-care, usual activities, pain and discomfort, and depression/anxiety). Scoring is on a 3-point scale (1=no health problems, 2=some or moderate problems, 3=major health problems). A preference value Index score is calculated using societal preference developed from a general population-based valuation studies. Index score ranges: United Kingdom (UK): -0.59 to 1.0, United States (US): -0.11 to 1.0, where 1 represents best possible health and 0 represents dead, with <0 interpreted as a health state "worse than dead." A Quality of Life Health State Score visual analog scale (VAS) was assessed, scores range from 0 to 100. Higher scores indicate better health state. Least Square (LS) Mean values were adjusted for treatment, pooled Investigator, baseline.

End point type	Secondary
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End point timeframe:

Baseline (Week 24), Week 49

End point values	Outcome Measure 8 Atomoxetine	Outcome Measure 8 Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	197	180		
Units: units on a scale				
least squares mean (standard error)				
UK population-based Index Score (n=194, 180)	0 (± 0.01)	0 (± 0.01)		
US population-based Index Score (n=194, 180)	0 (± 0.01)	0 (± 0.01)		
Health State Score (N=197, 179)	4.6 (± 1.21)	3.2 (± 1.19)		

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

B4Z-MC-LYDO

Assessment type	Systematic
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### Dictionary used

Dictionary name	MedDRA
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Dictionary version	16.0
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### Reporting groups

Reporting group title	Atomoxetine_Randomization Phase
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Reporting group description: -

Reporting group title	Placebo_Randomization Phase
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Reporting group description: -

Reporting group title	Atomoxetine_Open-label Phase
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Reporting group description: -

Reporting group title	Atomoxetine_Open-label Extension Phase
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Reporting group description: -

Serious adverse events	Atomoxetine_Randomization Phase	Placebo_Randomization Phase	Atomoxetine_Open-label Phase
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 266 (2.63%)	3 / 258 (1.16%)	29 / 2011 (1.44%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
intraductal proliferative breast lesion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			

bunion operation alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	  0 / 266 (0.00%) 0 / 0 0 / 0	  0 / 258 (0.00%) 0 / 0 0 / 0	  0 / 2011 (0.00%) 0 / 0 0 / 0
hospitalisation alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	  0 / 266 (0.00%) 0 / 0 0 / 0	  0 / 258 (0.00%) 0 / 0 0 / 0	  0 / 2011 (0.00%) 0 / 0 0 / 0
skin neoplasm excision alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	  0 / 266 (0.00%) 0 / 0 0 / 0	  0 / 258 (0.00%) 0 / 0 0 / 0	  0 / 2011 (0.00%) 0 / 0 0 / 0
tonsillectomy alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	  1 / 266 (0.38%) 0 / 1 0 / 0	  0 / 258 (0.00%) 0 / 0 0 / 0	  0 / 2011 (0.00%) 0 / 0 0 / 0
Reproductive system and breast disorders uterine polyp alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[1]</sup> occurrences causally related to treatment / all deaths causally related to treatment / all	  0 / 115 (0.00%) 0 / 0 0 / 0	  0 / 103 (0.00%) 0 / 0 0 / 0	  0 / 827 (0.00%) 0 / 0 0 / 0
Respiratory, thoracic and mediastinal disorders dyspnoea alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences causally related to treatment / all deaths causally related to treatment / all	  0 / 266 (0.00%) 0 / 0 0 / 0	  0 / 258 (0.00%) 0 / 0 0 / 0	  0 / 2011 (0.00%) 0 / 0 0 / 0
Psychiatric disorders			

alcohol abuse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depressive symptom			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (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
hallucination, auditory			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (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
restlessness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicidal ideation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
accidental overdose			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
diaphragmatic injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
fall			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
foot fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intentional overdose			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
lower limb fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (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
meniscus injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
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 alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (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
splenic injury alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
toxicity to various agents alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (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 disorders			
myocardial infarction alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	1 / 258 (0.39%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
palpitations alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
cerebellar infarction alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
convulsion alternative dictionary used: MedDRA 16.0			



subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
hypoesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
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			
gastroesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intestinal obstruction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
umbilical hernia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (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
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (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
hepatitis alcoholic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
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			
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
intervertebral disc protrusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
erysipelas			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
peritonsillar abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

<b>Serious adverse events</b>	Atomoxetine_Open-label Extension Phase		
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 180 (7.78%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	1		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
intraductal proliferative breast lesion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
haemorrhage			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
bunion operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
hospitalisation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
skin neoplasm excision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
tonsillectomy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Reproductive system and breast disorders			
uterine polyp			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[1]</sup>	1 / 85 (1.18%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
dyspnoea			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
alcohol abuse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
depressive symptom			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
hallucination, auditory			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
restlessness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
suicidal ideation			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
accidental overdose			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
diaphragmatic injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
fall			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
foot fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
intentional overdose			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
lower limb fracture			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
meniscus injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
road traffic accident			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
splenic injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
toxicity to various agents			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	1 / 1		
Cardiac disorders			
myocardial infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
palpitations			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
cerebellar infarction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
convulsion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
hypoaesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
intestinal obstruction			
alternative dictionary used: MedDRA 16.0			



subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
umbilical hernia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
cholecystitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
hepatitis alcoholic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
angioedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
intervertebral disc protrusion			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
appendicitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
erysipelas			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
peritonsillar abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Notes:

[1] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed to this adverse event. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

Frequency threshold for reporting non-serious adverse events: 1 %

Non-serious adverse events	Atomoxetine_Randomization Phase	Placebo_Randomization Phase	Atomoxetine_Open-label Phase
Total subjects affected by non-serious adverse events			
subjects affected / exposed	120 / 266 (45.11%)	96 / 258 (37.21%)	1611 / 2011 (80.11%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
uterine leiomyoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[2]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	1 / 827 (0.12%)
occurrences (all)	0	0	1
Vascular disorders			
flushing			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	14 / 2011 (0.70%)
occurrences (all)	0	0	15
haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
hot flush			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 266 (1.13%)	0 / 258 (0.00%)	56 / 2011 (2.78%)
occurrences (all)	3	0	61
hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	27 / 2011 (1.34%)
occurrences (all)	1	0	28
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	0	0	5
lymphoedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
orthostatic hypotension			
alternative dictionary used:			

MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
pallor			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
peripheral coldness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	16 / 2011 (0.80%)
occurrences (all)	0	0	19
varicose vein			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
abdominal hernia repair			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
abscess drainage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
angioplasty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
artificial crown procedure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
breast prosthesis implantation			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
central nervous system stimulation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
cleft palate repair			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
dental care			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	3
dental implantation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
dental operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
gastritis prophylaxis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
intervertebral disc operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
knee operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1

lipoma excision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
nasal septal operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
renal artery angioplasty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
renal stone removal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
sinus operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
skin neoplasm excision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
surgery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
tooth extraction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	5 / 2011 (0.25%)
occurrences (all)	0	1	7
wisdom teeth removal			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed occurrences (all)	1 / 266 (0.38%) 1	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
Pregnancy, puerperium and perinatal conditions			
pregnancy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[3]</sup>	0 / 115 (0.00%)	1 / 103 (0.97%)	7 / 827 (0.85%)
occurrences (all)	0	1	7
vomiting in pregnancy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[4]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	1 / 827 (0.12%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	17 / 2011 (0.85%)
occurrences (all)	1	0	20
chest discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	8 / 2011 (0.40%)
occurrences (all)	0	0	9
chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	12 / 2011 (0.60%)
occurrences (all)	0	1	12
chills			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	57 / 2011 (2.83%)
occurrences (all)	0	0	60
crying			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	5 / 2011 (0.25%)
occurrences (all)	0	1	5
device extrusion			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
drug ineffective			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
fatigue			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	3 / 258 (1.16%)	262 / 2011 (13.03%)
occurrences (all)	1	3	292
feeling abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	7 / 2011 (0.35%)
occurrences (all)	0	0	7
feeling cold			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	16 / 2011 (0.80%)
occurrences (all)	0	0	18
feeling hot			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	6 / 2011 (0.30%)
occurrences (all)	0	0	6
feeling jittery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	19 / 2011 (0.94%)
occurrences (all)	0	0	20
feeling of body temperature change			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4



feeling of relaxation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
hernia pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
hunger			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
influenza like illness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	1 / 258 (0.39%)	11 / 2011 (0.55%)
occurrences (all)	3	1	11
irritability			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	0 / 258 (0.00%)	80 / 2011 (3.98%)
occurrences (all)	2	0	87
malaise			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	46 / 2011 (2.29%)
occurrences (all)	1	0	57
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	2 / 258 (0.78%)	4 / 2011 (0.20%)
occurrences (all)	0	2	4
pain			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	4 / 2011 (0.20%)
occurrences (all)	0	1	4
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 266 (1.50%)	2 / 258 (0.78%)	16 / 2011 (0.80%)
occurrences (all)	4	2	17
secretion discharge			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
sense of oppression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
sluggishness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	0	0	5
temperature intolerance			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
temperature regulation disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
therapeutic response unexpected			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
thirst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	20 / 2011 (0.99%)
occurrences (all)	0	0	20

thirst decreased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	2 / 2011 (0.10%) 2
xerosis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
Immune system disorders allergy to arthropod sting alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
allergy to chemicals alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 266 (0.38%) 1	0 / 258 (0.00%) 0	0 / 2011 (0.00%) 0
food allergy alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
house dust allergy alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
hypersensitivity alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	7 / 2011 (0.35%) 7
multiple allergies alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
seasonal allergy alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 266 (0.75%)	1 / 258 (0.39%)	16 / 2011 (0.80%)
occurrences (all)	2	1	16
smoke sensitivity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
Social circumstances			
corrective lens user			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
denture wearer			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
educational problem			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
job dissatisfaction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
miscarriage of partner			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
stress at work			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
tobacco user			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[5]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	1 / 827 (0.12%)
occurrences (all)	0	0	1
breast disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
breast pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
breast tenderness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
dysmenorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[6]</sup>	1 / 115 (0.87%)	1 / 103 (0.97%)	19 / 827 (2.30%)
occurrences (all)	2	1	23
dyspareunia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	7
ejaculation delayed			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[7]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	7 / 1184 (0.59%)
occurrences (all)	0	0	8
ejaculation disorder			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed <sup>[8]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	25 / 1184 (2.11%)
occurrences (all)	0	0	29
ejaculation failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[9]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	1 / 1184 (0.08%)
occurrences (all)	0	0	1
epididymitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[10]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	2 / 1184 (0.17%)
occurrences (all)	0	0	2
erectile dysfunction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[11]</sup>	3 / 151 (1.99%)	0 / 155 (0.00%)	99 / 1184 (8.36%)
occurrences (all)	3	0	103
erection increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[12]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	1 / 1184 (0.08%)
occurrences (all)	0	0	1
genital pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	6 / 2011 (0.30%)
occurrences (all)	0	0	7
haematospermia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[13]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	1 / 1184 (0.08%)
occurrences (all)	0	0	1
menorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[14]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	4 / 827 (0.48%)
occurrences (all)	0	0	4
menstrual disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[15]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	2 / 827 (0.24%)
occurrences (all)	0	0	3

menstruation delayed			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[16]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	2 / 827 (0.24%)
occurrences (all)	0	0	2
menstruation irregular			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[17]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	1 / 827 (0.12%)
occurrences (all)	0	0	1
metrorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[18]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	2 / 827 (0.24%)
occurrences (all)	0	0	2
nipple disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
oligomenorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[19]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	1 / 827 (0.12%)
occurrences (all)	0	0	1
ovarian cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[20]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	1 / 827 (0.12%)
occurrences (all)	0	0	1
painful erection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[21]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	4 / 1184 (0.34%)
occurrences (all)	0	0	4
penile size reduced			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[22]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	1 / 1184 (0.08%)
occurrences (all)	0	0	1
penile swelling			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed <sup>[23]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	0 / 1184 (0.00%)
occurrences (all)	0	0	0
penis disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[24]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	1 / 1184 (0.08%)
occurrences (all)	0	0	1
polymenorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[25]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	1 / 827 (0.12%)
occurrences (all)	0	0	1
premenstrual cramps			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[26]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	1 / 827 (0.12%)
occurrences (all)	0	0	1
prostatic pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[27]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	1 / 1184 (0.08%)
occurrences (all)	0	0	1
prostatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[28]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	1 / 1184 (0.08%)
occurrences (all)	0	0	1
retrograde ejaculation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[29]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	3 / 1184 (0.25%)
occurrences (all)	0	0	5
scrotal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[30]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	3 / 1184 (0.25%)
occurrences (all)	0	0	4
scrotal swelling			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[31]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	1 / 1184 (0.08%)
occurrences (all)	0	0	1



sexual dysfunction alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	16 / 2011 (0.80%) 16
spermatorrhoea alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[32]</sup> occurrences (all)	0 / 151 (0.00%) 0	0 / 155 (0.00%) 0	2 / 1184 (0.17%) 3
testicular pain alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[33]</sup> occurrences (all)	0 / 151 (0.00%) 0	0 / 155 (0.00%) 0	20 / 1184 (1.69%) 21
testicular swelling alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[34]</sup> occurrences (all)	0 / 151 (0.00%) 0	0 / 155 (0.00%) 0	1 / 1184 (0.08%) 2
testicular torsion alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[35]</sup> occurrences (all)	0 / 151 (0.00%) 0	0 / 155 (0.00%) 0	1 / 1184 (0.08%) 1
vaginal discharge alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[36]</sup> occurrences (all)	0 / 115 (0.00%) 0	0 / 103 (0.00%) 0	2 / 827 (0.24%) 2
vaginal haemorrhage alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[37]</sup> occurrences (all)	1 / 115 (0.87%) 1	0 / 103 (0.00%) 0	2 / 827 (0.24%) 2
vulvovaginal dryness alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[38]</sup> occurrences (all)	0 / 115 (0.00%) 0	0 / 103 (0.00%) 0	0 / 827 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			

asphyxia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
asthma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	6 / 2011 (0.30%)
occurrences (all)	0	0	7
bronchospasm			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 266 (1.88%)	1 / 258 (0.39%)	22 / 2011 (1.09%)
occurrences (all)	6	1	23
dry throat			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
dysphonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
dyspnoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	11 / 2011 (0.55%)
occurrences (all)	1	0	12
epistaxis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	0	0	7
hyperventilation			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
increased upper airway secretion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
nasal congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	2 / 258 (0.78%)	17 / 2011 (0.85%)
occurrences (all)	1	2	18
nasal discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
nasal dryness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
nasal obstruction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
nasal polyps			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
oropharyngeal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 266 (1.88%)	4 / 258 (1.55%)	20 / 2011 (0.99%)
occurrences (all)	5	5	20
pharyngeal inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	2

pharyngeal oedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
pleurisy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
pneumothorax			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
productive cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
respiratory disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
respiratory tract congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	2 / 2011 (0.10%)
occurrences (all)	0	1	2
rhinitis allergic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	1 / 258 (0.39%)	5 / 2011 (0.25%)
occurrences (all)	1	1	5
rhinitis seasonal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
rhinorrhoea			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	19 / 2011 (0.94%)
occurrences (all)	0	0	23
sinus congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	1	0	5
sneezing			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	0	0	5
snoring			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
tachypnoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
throat irritation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	2
throat tightness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
upper-airway cough syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
yawning			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	8 / 2011 (0.40%)
occurrences (all)	1	0	9

Psychiatric disorders			
abnormal behaviour			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
abnormal dreams			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	34 / 2011 (1.69%)
occurrences (all)	0	0	35
adjustment disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
affect lability			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	12 / 2011 (0.60%)
occurrences (all)	0	0	12
affective disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	1 / 2011 (0.05%)
occurrences (all)	0	1	1
aggression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	14 / 2011 (0.70%)
occurrences (all)	0	0	14
agitation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	28 / 2011 (1.39%)
occurrences (all)	0	0	32
alcohol abuse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
alcohol problem			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
alcoholic hangover			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	3
alcoholism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
anger			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
anorgasmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	3
anxiety			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 266 (1.13%)	3 / 258 (1.16%)	60 / 2011 (2.98%)
occurrences (all)	3	3	62
apathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	14 / 2011 (0.70%)
occurrences (all)	0	0	16
attention deficit/hyperactivity disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	1	0	4
bradyphrenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2

bruxism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	4
burnout syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
confusional state			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	0	0	5
daydreaming			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
decreased activity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
decreased interest			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
depressed mood			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	2 / 258 (0.78%)	56 / 2011 (2.78%)
occurrences (all)	0	2	62
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	3 / 258 (1.16%)	34 / 2011 (1.69%)
occurrences (all)	2	4	34
depressive symptom			
alternative dictionary used: MedDRA 16.0			



subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	4 / 2011 (0.20%)
occurrences (all)	0	1	4
derealisation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
disinhibition			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
disorientation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
dissociation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
distractibility			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
disturbance in sexual arousal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
drug dependence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
dysphemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2

dysphoria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
eating disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
emotional disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	0	0	5
euphoric mood			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
fear			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
feelings of worthlessness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
hallucination, auditory			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
hallucination, visual			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
hypersexuality			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
hypomania			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
illusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
impatience			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
impulsive behaviour			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4
inappropriate affect			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
initial insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 266 (1.50%)	0 / 258 (0.00%)	34 / 2011 (1.69%)
occurrences (all)	4	0	40
insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 266 (1.13%)	1 / 258 (0.39%)	177 / 2011 (8.80%)
occurrences (all)	3	1	209
intentional self-injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1

laziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
libido decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	2 / 258 (0.78%)	61 / 2011 (3.03%)
occurrences (all)	2	2	65
libido increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
listless			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	0	0	5
logorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
loss of libido			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	9 / 2011 (0.45%)
occurrences (all)	0	0	9
magical thinking			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
major depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
middle insomnia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	2 / 266 (0.75%)	0 / 258 (0.00%)	33 / 2011 (1.64%)
occurrences (all)	2	0	35
mood altered			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4
mood swings			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	12 / 2011 (0.60%)
occurrences (all)	0	0	12
mutism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
nervousness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	9 / 2011 (0.45%)
occurrences (all)	1	0	9
nightmare			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	11 / 2011 (0.55%)
occurrences (all)	1	0	11
orgasm abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	7 / 2011 (0.35%)
occurrences (all)	1	0	7
orgasmic sensation decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
panic attack			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	8 / 2011 (0.40%)
occurrences (all)	0	1	8

panic disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
post-traumatic stress disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
poverty of speech			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
premature ejaculation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[39]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	20 / 1184 (1.69%)
occurrences (all)	0	0	24
pressure of speech			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
psychiatric symptom			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
psychomotor retardation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
restlessness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	27 / 2011 (1.34%)
occurrences (all)	1	0	34
self-injurious ideation			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
sleep attacks			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
sleep disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	1 / 258 (0.39%)	71 / 2011 (3.53%)
occurrences (all)	1	1	82
sleep talking			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
staring			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
stress			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	6 / 2011 (0.30%)
occurrences (all)	1	0	7
suicidal ideation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	7 / 2011 (0.35%)
occurrences (all)	0	0	7
tachyphrenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	4
tearfulness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2

tension alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	7 / 2011 (0.35%) 7
terminal insomnia alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	18 / 2011 (0.90%) 21
tic alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	1 / 258 (0.39%) 1	3 / 2011 (0.15%) 3
trance alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
violence-related symptom alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
Hepatobiliary disorders biliary colic alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	0 / 2011 (0.00%) 0
cholecystitis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	0 / 2011 (0.00%) 0
cholelithiasis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
hepatic cyst alternative dictionary used: MedDRA 16.0			



subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
Investigations			
arthroscopy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
blood cholesterol increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
blood glucose increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
blood pressure decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
blood pressure diastolic increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
blood pressure increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 266 (1.50%)	0 / 258 (0.00%)	13 / 2011 (0.65%)
occurrences (all)	6	0	13
blood pressure orthostatic decreased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
blood urine present			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
body temperature decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
colonoscopy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	1	0	2
electrocardiogram pr interval			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
electrocardiogram qrs complex prolonged			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
electrocardiogram abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
gastric ph decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
hiv test positive			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1

heart rate increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	21 / 2011 (1.04%) 24
heart rate irregular alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	1 / 258 (0.39%) 1	0 / 2011 (0.00%) 0
intraocular pressure increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
qrs axis abnormal alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 266 (0.38%) 1	0 / 258 (0.00%) 0	0 / 2011 (0.00%) 0
respiratory rate increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
serum ferritin alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
weight decreased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 266 (0.38%) 1	1 / 258 (0.39%) 1	39 / 2011 (1.94%) 39
weight increased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	3 / 266 (1.13%) 3	1 / 258 (0.39%) 1	13 / 2011 (0.65%) 13
Injury, poisoning and procedural complications			

animal bite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
ankle fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
arthropod bite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	1	0	2
arthropod sting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
bite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
bone contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
burns first degree			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
chest injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
clavicle fracture			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
concussion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 266 (1.88%)	0 / 258 (0.00%)	8 / 2011 (0.40%)
occurrences (all)	5	0	8
craniocerebral injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
electric shock			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
epicondylitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	2	0	1
excoriation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	1	0	2
exposure during pregnancy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
exposure via father			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0

eye injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
fall			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4
foot fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
foreign body in eye			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
frostbite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
hand fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	2 / 258 (0.78%)	6 / 2011 (0.30%)
occurrences (all)	0	2	6
heat stroke			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
joint injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4
laceration			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	7 / 2011 (0.35%)
occurrences (all)	0	1	11
ligament injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
ligament rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	2 / 258 (0.78%)	5 / 2011 (0.25%)
occurrences (all)	1	2	5
limb injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
meniscus injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	1	0	1
muscle rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
muscle strain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	1 / 258 (0.39%)	4 / 2011 (0.20%)
occurrences (all)	1	1	4
nail injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1

overdose			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
periorbital haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
post procedural complication			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	3 / 2011 (0.15%)
occurrences (all)	0	1	3
procedural pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4
rib fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
road traffic accident			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	1 / 258 (0.39%)	3 / 2011 (0.15%)
occurrences (all)	1	1	3
scar			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
soft tissue injury			
alternative dictionary used: MedDRA 16.0			



subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
thermal burn			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
tooth fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
tooth injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
wound			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
wrist fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
Cardiac disorders			
angina pectoris			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	2	0	2
bradycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
cardiac disorder			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
cardiovascular disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4
extrasystoles			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	5
palpitations			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	1 / 258 (0.39%)	83 / 2011 (4.13%)
occurrences (all)	1	1	90
sinus arrhythmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
sinus bradycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
sinus tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 266 (1.13%)	1 / 258 (0.39%)	70 / 2011 (3.48%)
occurrences (all)	4	1	73
Nervous system disorders			
ageusia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
akathisia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
akinesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
apallic syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
aphasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
autonomic nervous system imbalance			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
balance disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
burning sensation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
carpal tunnel syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0

circadian rhythm sleep disorder alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
clumsiness alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	5 / 2011 (0.25%) 6
cognitive disorder alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	0 / 2011 (0.00%) 0
convulsion alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	2 / 2011 (0.10%) 2
coordination abnormal alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
depressed level of consciousness alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	3 / 2011 (0.15%) 3
disturbance in attention alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	2 / 266 (0.75%) 2	0 / 258 (0.00%) 0	11 / 2011 (0.55%) 12
dizziness alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 266 (0.38%) 1	2 / 258 (0.78%) 2	170 / 2011 (8.45%) 195
dizziness postural alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
drooling			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
dysaesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
dysarthria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
dysgeusia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	20 / 2011 (0.99%)
occurrences (all)	1	0	22
dyskinesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	2
formication			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
head discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4
head titubation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1

headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	13 / 266 (4.89%)	11 / 258 (4.26%)	347 / 2011 (17.26%)
occurrences (all)	15	11	482
hypersomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	6 / 2011 (0.30%)
occurrences (all)	0	0	6
hypertonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	3 / 2011 (0.15%)
occurrences (all)	0	1	3
hypoesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	11 / 2011 (0.55%)
occurrences (all)	0	0	12
hypogeusia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
hypotonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
irregular sleep phase			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
lethargy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	11 / 2011 (0.55%)
occurrences (all)	0	0	11
loss of consciousness			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	1	0	1
memory impairment			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	10 / 2011 (0.50%)
occurrences (all)	1	0	10
mental impairment			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	0	0	5
migraine			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	1 / 258 (0.39%)	26 / 2011 (1.29%)
occurrences (all)	3	1	46
muscle contractions involuntary			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
myoclonus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
neurological symptom			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
orthostatic intolerance			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
paraesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	74 / 2011 (3.68%)
occurrences (all)	1	0	76

parosmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4
poor quality sleep			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	15 / 2011 (0.75%)
occurrences (all)	0	0	15
psychomotor hyperactivity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	2 / 2011 (0.10%)
occurrences (all)	0	1	2
psychomotor skills impaired			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
restless legs syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
sciatica			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	2 / 258 (0.78%)	1 / 2011 (0.05%)
occurrences (all)	0	2	1
sedation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	26 / 2011 (1.29%)
occurrences (all)	0	0	27
sensory disturbance			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	2
sinus headache			
alternative dictionary used: MedDRA 16.0			



subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	0	0	5
somnolence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	1 / 258 (0.39%)	112 / 2011 (5.57%)
occurrences (all)	1	1	126
speech disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
syncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	1	0	3
tension headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	8 / 2011 (0.40%)
occurrences (all)	0	0	8
tremor			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	25 / 2011 (1.24%)
occurrences (all)	0	1	26
trigeminal neuralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
tunnel vision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
leukopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
lymphadenitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
lymphadenopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	2	0	3
splenic cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
ear discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
ear pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
external ear inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
hyperacusis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
hypoacusis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
inner ear inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
motion sickness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	2
sudden hearing loss			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
tinnitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	11 / 2011 (0.55%)
occurrences (all)	0	1	11
vertigo			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	38 / 2011 (1.89%)
occurrences (all)	0	1	46
Eye disorders			
abnormal sensation in eye			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	2
accommodation disorder			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
blepharitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
blepharospasm			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
blindness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	8 / 2011 (0.40%)
occurrences (all)	0	1	8
diplopia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
dry eye			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4
excessive eye blinking			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
eye discharge			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1

eye irritation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
eye pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	1	0	1
glaucoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
iridocyclitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
lacrimation increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4
miosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
mydriasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
ocular discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
ocular hyperaemia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
photophobia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
vision blurred			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	32 / 2011 (1.59%)
occurrences (all)	0	0	32
visual acuity reduced			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	0	0	5
visual impairment			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	29 / 2011 (1.44%)
occurrences (all)	1	0	30
abdominal distension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	7 / 2011 (0.35%)
occurrences (all)	0	0	7
abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	38 / 2011 (1.89%)
occurrences (all)	0	0	41
abdominal pain lower			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 266 (0.38%)	1 / 258 (0.39%)	3 / 2011 (0.15%)
occurrences (all)	1	1	3
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	2 / 258 (0.78%)	61 / 2011 (3.03%)
occurrences (all)	2	2	73
abdominal rigidity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
aphthous stomatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4
barrett's oesophagus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
breath odour			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
chapped lips			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	93 / 2011 (4.62%)
occurrences (all)	1	0	99
crohn's disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1

defaecation urgency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
dental caries			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	2	0	1
diarrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 266 (1.50%)	5 / 258 (1.94%)	53 / 2011 (2.64%)
occurrences (all)	4	5	60
dry mouth			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 266 (1.13%)	2 / 258 (0.78%)	342 / 2011 (17.01%)
occurrences (all)	4	2	368
dyspepsia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	65 / 2011 (3.23%)
occurrences (all)	1	0	72
dysphagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
epigastric discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
eructation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
faeces hard			
alternative dictionary used: MedDRA 16.0			



subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
flatulence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	10 / 2011 (0.50%)
occurrences (all)	1	0	11
food poisoning			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
frequent bowel movements			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
gastric disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	7 / 2011 (0.35%)
occurrences (all)	0	0	8
gastritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	1	0	4
gastrointestinal disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	0	0	6
gastrointestinal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	4 / 2011 (0.20%)
occurrences (all)	0	1	5
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	12 / 2011 (0.60%)
occurrences (all)	1	0	14

gingival bleeding			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
gingival inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
gingival pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
haematochezia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	4
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
haemorrhoids			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	1	0	5
hyperchlorhydria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
hypoesthesia oral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
inguinal hernia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
irritable bowel syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 266 (2.26%)	3 / 258 (1.16%)	552 / 2011 (27.45%)
occurrences (all)	6	4	707
oesophagitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
oral disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
oral mucosal blistering			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
oral pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
paraesthesia oral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
periodontal disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1

reflux gastritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
saliva altered			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
salivary hypersecretion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
stomatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
tooth disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
toothache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	2 / 258 (0.78%)	23 / 2011 (1.14%)
occurrences (all)	1	2	25
umbilical hernia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	3 / 258 (1.16%)	82 / 2011 (4.08%)
occurrences (all)	1	3	96
Skin and subcutaneous tissue disorders			

acne			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	12 / 2011 (0.60%)
occurrences (all)	0	0	12
alopecia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	1	0	5
cold sweat			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	0	0	5
dandruff			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
dermatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
dermatitis acneiform			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
dermatitis allergic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	1	0	3
dermatitis atopic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
dry skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	6 / 2011 (0.30%)
occurrences (all)	0	1	6
eczema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	6 / 2011 (0.30%)
occurrences (all)	0	0	6
erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
guttate psoriasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
heat rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
hyperhidrosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	0 / 258 (0.00%)	180 / 2011 (8.95%)
occurrences (all)	2	0	196
hyperkeratosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
hypertrichosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1

lichen planus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
neurodermatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
night sweats			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	2 / 258 (0.78%)	3 / 2011 (0.15%)
occurrences (all)	0	2	3
pain of skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
photosensitivity reaction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4
piloerection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	23 / 2011 (1.14%)
occurrences (all)	0	0	25
pityriasis rosea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	16 / 2011 (0.80%)
occurrences (all)	1	0	16
pruritus generalised			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
psoriasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	12 / 2011 (0.60%)
occurrences (all)	1	0	12
rash erythematous			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
rash pruritic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
rosacea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
skin atrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
skin burning sensation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
skin disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2



skin lesion alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	2 / 2011 (0.10%) 2
skin odour abnormal alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	2 / 2011 (0.10%) 3
solar dermatitis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	0 / 2011 (0.00%) 0
urticaria alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 266 (0.38%) 1	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
Renal and urinary disorders bladder dysfunction alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 266 (0.38%) 1	0 / 258 (0.00%) 0	0 / 2011 (0.00%) 0
chromaturia alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	4 / 2011 (0.20%) 4
dysuria alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 266 (0.38%) 1	0 / 258 (0.00%) 0	49 / 2011 (2.44%) 54
haematuria alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
incontinence alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
micturition disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	6 / 2011 (0.30%)
occurrences (all)	1	0	6
micturition urgency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	1	0	3
nocturia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
pollakiuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	13 / 2011 (0.65%)
occurrences (all)	0	0	13
polyuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
renal colic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	2
renal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
semenuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[40]</sup>	0 / 151 (0.00%)	0 / 155 (0.00%)	3 / 1184 (0.25%)
occurrences (all)	0	0	3

urethral discharge			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
urinary hesitation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	0 / 258 (0.00%)	43 / 2011 (2.14%)
occurrences (all)	2	0	46
urinary incontinence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
urinary retention			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	21 / 2011 (1.04%)
occurrences (all)	0	0	22
urinary tract disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4
urinary tract obstruction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
urine abnormality			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
urine flow decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	14 / 2011 (0.70%)
occurrences (all)	0	0	14
urine odour abnormal			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	2 / 2011 (0.10%) 2
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	2 / 258 (0.78%) 2	1 / 2011 (0.05%) 1
hyperthyroidism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
hypothyroidism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	2 / 2011 (0.10%) 2
thyroid pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	2 / 266 (0.75%) 2	1 / 258 (0.39%) 1	15 / 2011 (0.75%) 15
arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	0 / 2011 (0.00%) 0
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed occurrences (all)	3 / 266 (1.13%) 3	7 / 258 (2.71%) 7	30 / 2011 (1.49%) 30
bursitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
chondropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
coccydynia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
compartment syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
groin pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	3 / 2011 (0.15%)
occurrences (all)	0	1	3
intervertebral disc protrusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
joint contracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
limb discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
monarthrititis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0

muscle contracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
muscle fatigue			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
muscle spasms			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	8 / 2011 (0.40%)
occurrences (all)	0	0	8
muscle tightness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	10 / 2011 (0.50%)
occurrences (all)	0	0	10
muscular weakness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	2
musculoskeletal chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
musculoskeletal discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
musculoskeletal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	9 / 2011 (0.45%)
occurrences (all)	0	1	9
musculoskeletal stiffness			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	1	0	2
myalgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	1 / 258 (0.39%)	16 / 2011 (0.80%)
occurrences (all)	1	1	20
myosclerosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
myositis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
neck pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	1 / 258 (0.39%)	6 / 2011 (0.30%)
occurrences (all)	1	1	6
osteitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	2 / 258 (0.78%)	5 / 2011 (0.25%)
occurrences (all)	2	2	5
pain in jaw			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2

periostitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
plantar fasciitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
rotator cuff syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
scoliosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
sensation of heaviness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
spinal osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
tendon pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
tendonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	3 / 2011 (0.15%)
occurrences (all)	0	1	3
tenosynovitis			
alternative dictionary used: MedDRA 16.0			



subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
torticollis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	1 / 2011 (0.05%)
occurrences (all)	0	1	1
acarodermatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
acute sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
acute tonsillitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
body tinea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 266 (1.13%)	2 / 258 (0.78%)	18 / 2011 (0.90%)
occurrences (all)	3	2	19
candidiasis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
chlamydial cervicitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[41]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	1 / 827 (0.12%)
occurrences (all)	0	0	1
chronic sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
cystitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	1 / 258 (0.39%)	8 / 2011 (0.40%)
occurrences (all)	1	1	8
ear infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	2	0	2
enteritis infectious			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
erythema migrans			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
fungus infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 266 (1.88%)	2 / 258 (0.78%)	24 / 2011 (1.19%)
occurrences (all)	5	2	24

gastroenteritis norovirus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
gastroenteritis viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	16 / 2011 (0.80%)
occurrences (all)	0	1	16
gastrointestinal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	4 / 2011 (0.20%)
occurrences (all)	0	0	4
gastrointestinal viral infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
genital herpes			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
genital infection fungal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
gingivitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	1	0	3
gonorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
helicobacter infection			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
herpes simplex			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
herpes virus infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
hordeolum			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	1	0	1
infected bites			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	1	0	0
infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
infection parasitic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 266 (3.01%)	6 / 258 (2.33%)	52 / 2011 (2.59%)
occurrences (all)	8	6	55

laryngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
localised infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
lower respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
lyme disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
mycoplasma infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	0 / 2011 (0.00%)
occurrences (all)	0	1	0
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	18 / 266 (6.77%)	13 / 258 (5.04%)	137 / 2011 (6.81%)
occurrences (all)	26	16	153
oral herpes			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	4
otitis media			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	0 / 258 (0.00%)	6 / 2011 (0.30%)
occurrences (all)	2	0	6
peritonsillar abscess			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
pertussis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	0 / 258 (0.00%)	8 / 2011 (0.40%)
occurrences (all)	2	0	8
pharyngitis streptococcal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	1 / 258 (0.39%)	4 / 2011 (0.20%)
occurrences (all)	0	1	4
pharyngotonsillitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	2	0	1
pyelonephritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	1	0	1
respiratory tract infection viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1

rhinitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	2 / 258 (0.78%)	13 / 2011 (0.65%)
occurrences (all)	1	2	13
rhinovirus infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
salpingo-oophoritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[42]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	1 / 827 (0.12%)
occurrences (all)	0	0	1
scarlet fever			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 266 (0.75%)	3 / 258 (1.16%)	23 / 2011 (1.14%)
occurrences (all)	2	4	24
skin infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
subcutaneous abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
tinea pedis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
tinea versicolour			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	1	0	3
tonsillitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	2 / 258 (0.78%)	9 / 2011 (0.45%)
occurrences (all)	1	2	9
tooth abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	3 / 2011 (0.15%)
occurrences (all)	0	0	3
tooth infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	5 / 2011 (0.25%)
occurrences (all)	1	0	5
tracheitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	11 / 266 (4.14%)	7 / 258 (2.71%)	57 / 2011 (2.83%)
occurrences (all)	13	7	62
urethritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	0 / 258 (0.00%)	12 / 2011 (0.60%)
occurrences (all)	2	0	12
vaginal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[43]</sup>	0 / 115 (0.00%)	0 / 103 (0.00%)	3 / 827 (0.36%)
occurrences (all)	0	0	3



viral infection alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	6 / 2011 (0.30%) 6
viral upper respiratory tract infection alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 266 (0.38%) 1	0 / 258 (0.00%) 0	5 / 2011 (0.25%) 5
vulvovaginal candidiasis alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[44]</sup> occurrences (all)	0 / 115 (0.00%) 0	0 / 103 (0.00%) 0	0 / 827 (0.00%) 0
wound infection alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 266 (0.38%) 1	0 / 258 (0.00%) 0	0 / 2011 (0.00%) 0
Metabolism and nutrition disorders acidosis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
decreased appetite alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 266 (0.38%) 1	1 / 258 (0.39%) 1	294 / 2011 (14.62%) 319
dehydration alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	0 / 258 (0.00%) 0	1 / 2011 (0.05%) 1
hypercholesterolaemia alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 266 (0.00%) 0	1 / 258 (0.39%) 1	2 / 2011 (0.10%) 2
hyperphagia alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	2 / 2011 (0.10%)
occurrences (all)	0	0	2
hypertriglyceridaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
hypoglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
increased appetite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 266 (0.38%)	3 / 258 (1.16%)	10 / 2011 (0.50%)
occurrences (all)	1	3	10
polydipsia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
tetany			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1
vitamin b12 deficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	0 / 2011 (0.00%)
occurrences (all)	0	0	0
vitamin d deficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 266 (0.00%)	0 / 258 (0.00%)	1 / 2011 (0.05%)
occurrences (all)	0	0	1

Non-serious adverse events	Atomoxetine_Open-label Extension Phase		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	119 / 180 (66.11%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
uterine leiomyoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[2]</sup>	0 / 85 (0.00%)		
occurrences (all)	0		
Vascular disorders			
flushing			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hot flush			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
hypertension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
lymphoedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
orthostatic hypotension			

<p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>		
<p>pallor</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>		
<p>peripheral coldness</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 180 (0.56%)</p> <p>1</p>		
<p>varicose vein</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 180 (0.56%)</p> <p>1</p>		
<p>Surgical and medical procedures</p> <p>abdominal hernia repair</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>		
<p>abscess drainage</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>		
<p>angioplasty</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>		
<p>artificial crown procedure</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>		
<p>breast prosthesis implantation</p> <p>alternative dictionary used: MedDRA 16.0</p>			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
central nervous system stimulation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
cleft palate repair			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dental care			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dental implantation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dental operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
gastritis prophylaxis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
intervertebral disc operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
knee operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		

lipoma excision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
nasal septal operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
renal artery angioplasty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
renal stone removal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sinus operation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
skin neoplasm excision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
surgery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
tooth extraction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
wisdom teeth removal			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Pregnancy, puerperium and perinatal conditions			
pregnancy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[3]</sup>	0 / 85 (0.00%)		
occurrences (all)	0		
vomiting in pregnancy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[4]</sup>	0 / 85 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
chest discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
chills			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
crying			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
device extrusion			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
drug ineffective			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
fatigue			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 180 (2.22%)		
occurrences (all)	5		
feeling abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
feeling cold			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
feeling hot			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
feeling jittery			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
feeling of body temperature change			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		



feeling of relaxation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hernia pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
hunger			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
influenza like illness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
irritability			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
malaise			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
pain			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
secretion discharge			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sense of oppression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sluggishness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
temperature intolerance			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
temperature regulation disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
therapeutic response unexpected			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
thirst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

thirst decreased alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
xerosis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
Immune system disorders allergy to arthropod sting alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
allergy to chemicals alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
food allergy alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
house dust allergy alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
hypersensitivity alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
multiple allergies alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
seasonal allergy alternative dictionary used: MedDRA 16.0			

<p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>smoke sensitivity</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 180 (0.56%)</p> <p>1</p> <p>0 / 180 (0.00%)</p> <p>0</p>		
<p>Social circumstances</p> <p>corrective lens user</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>denture wearer</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>educational problem</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>job dissatisfaction</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>miscarriage of partner</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>stress at work</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>tobacco user</p> <p>alternative dictionary used: MedDRA 16.0</p>	<p>0 / 180 (0.00%)</p> <p>0</p> <p>0 / 180 (0.00%)</p> <p>0</p> <p>0 / 180 (0.00%)</p> <p>0</p> <p>0 / 180 (0.00%)</p> <p>0</p> <p>1 / 180 (0.56%)</p> <p>1</p> <p>1 / 180 (0.56%)</p> <p>1</p>		

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[5]</sup>	0 / 85 (0.00%)		
occurrences (all)	0		
breast disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
breast pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
breast tenderness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dysmenorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[6]</sup>	2 / 85 (2.35%)		
occurrences (all)	2		
dyspareunia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
ejaculation delayed			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[7]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		
ejaculation disorder			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed <sup>[8]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		
ejaculation failure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[9]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		
epididymitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[10]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		
erectile dysfunction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[11]</sup>	2 / 95 (2.11%)		
occurrences (all)	2		
erection increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[12]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		
genital pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
haematospermia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[13]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		
menorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[14]</sup>	1 / 85 (1.18%)		
occurrences (all)	1		
menstrual disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[15]</sup>	1 / 85 (1.18%)		
occurrences (all)	7		

menstruation delayed			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[16]</sup>	0 / 85 (0.00%)		
occurrences (all)	0		
menstruation irregular			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[17]</sup>	0 / 85 (0.00%)		
occurrences (all)	0		
metrorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[18]</sup>	0 / 85 (0.00%)		
occurrences (all)	0		
nipple disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
oligomenorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[19]</sup>	0 / 85 (0.00%)		
occurrences (all)	0		
ovarian cyst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[20]</sup>	0 / 85 (0.00%)		
occurrences (all)	0		
painful erection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[21]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		
penile size reduced			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[22]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		
penile swelling			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed <sup>[23]</sup>	1 / 95 (1.05%)		
occurrences (all)	1		
penis disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[24]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		
polymenorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[25]</sup>	0 / 85 (0.00%)		
occurrences (all)	0		
premenstrual cramps			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[26]</sup>	0 / 85 (0.00%)		
occurrences (all)	0		
prostatic pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[27]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		
prostatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[28]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		
retrograde ejaculation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[29]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		
scrotal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[30]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		
scrotal swelling			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[31]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		



sexual dysfunction alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
spermatorrhoea alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[32]</sup> occurrences (all)	0 / 95 (0.00%) 0		
testicular pain alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[33]</sup> occurrences (all)	0 / 95 (0.00%) 0		
testicular swelling alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[34]</sup> occurrences (all)	0 / 95 (0.00%) 0		
testicular torsion alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[35]</sup> occurrences (all)	0 / 95 (0.00%) 0		
vaginal discharge alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[36]</sup> occurrences (all)	0 / 85 (0.00%) 0		
vaginal haemorrhage alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[37]</sup> occurrences (all)	0 / 85 (0.00%) 0		
vulvovaginal dryness alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[38]</sup> occurrences (all)	1 / 85 (1.18%) 1		
Respiratory, thoracic and mediastinal disorders			

asphyxia			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
asthma			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
bronchospasm			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
cough			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
dry throat			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dysphonia			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dyspnoea			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
epistaxis			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hyperventilation			
alternative dictionary used:			
MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
increased upper airway secretion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
nasal congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
nasal discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
nasal dryness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
nasal obstruction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
nasal polyps			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
oropharyngeal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 180 (3.33%)		
occurrences (all)	6		
pharyngeal inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

pharyngeal oedema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
pleurisy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
pneumothorax			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
productive cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
respiratory disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
respiratory tract congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
rhinitis allergic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
rhinitis seasonal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
rhinorrhoea			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sinus congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sneezing			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
snoring			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
tachypnoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
throat irritation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
throat tightness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
upper-airway cough syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
yawning			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

Psychiatric disorders			
abnormal behaviour			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
abnormal dreams			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
adjustment disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
affect lability			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
affective disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
aggression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
agitation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
alcohol abuse			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
alcohol problem			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
alcoholic hangover			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
alcoholism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
anger			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
anorgasmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
anxiety			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
apathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
attention deficit/hyperactivity disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
bradyphrenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

bruxism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
burnout syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
confusional state			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
daydreaming			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
decreased activity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
decreased interest			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
depressed mood			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 180 (2.22%)		
occurrences (all)	5		
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
depressive symptom			
alternative dictionary used: MedDRA 16.0			



subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
derealisation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
disinhibition			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
disorientation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dissociation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
distractibility			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
disturbance in sexual arousal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
drug dependence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dysphemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

dysphoria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
eating disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
emotional disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
euphoric mood			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
fear			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
feelings of worthlessness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
hallucination, auditory			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hallucination, visual			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hypersexuality			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hypomania			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
illusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
impatience			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
impulsive behaviour			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
inappropriate affect			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
initial insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 180 (2.22%)		
occurrences (all)	6		
intentional self-injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

laziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
libido decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
libido increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
listless			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
logorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
loss of libido			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
magical thinking			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
major depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
middle insomnia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	3 / 180 (1.67%)		
occurrences (all)	3		
mood altered			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
mood swings			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
mutism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
nervousness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	3		
nightmare			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
orgasm abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
orgasmic sensation decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
panic attack			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

panic disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
post-traumatic stress disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
poverty of speech			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
premature ejaculation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[39]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		
pressure of speech			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
psychiatric symptom			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
psychomotor retardation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
restlessness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	3		
self-injurious ideation			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sleep attacks			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sleep disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 180 (2.78%)		
occurrences (all)	5		
sleep talking			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
staring			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
stress			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
suicidal ideation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
tachyphrenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
tearfulness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

tension alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
terminal insomnia alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
tic alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
trance alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
violence-related symptom alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
Hepatobiliary disorders biliary colic alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 180 (0.56%) 1		
cholecystitis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 180 (0.56%) 1		
cholelithiasis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
hepatic cyst alternative dictionary used: MedDRA 16.0			



subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
Investigations			
arthroscopy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
blood cholesterol increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
blood glucose increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
blood pressure decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
blood pressure diastolic increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
blood pressure increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 180 (1.67%)		
occurrences (all)	3		
blood pressure orthostatic decreased			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
blood urine present			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
body temperature decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
colonoscopy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
electrocardiogram pr interval			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
electrocardiogram qrs complex prolonged			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
electrocardiogram abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
gastric ph decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hiv test positive			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

heart rate increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
heart rate irregular			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
intraocular pressure increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
qrs axis abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
respiratory rate increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
serum ferritin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
weight decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
weight increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
Injury, poisoning and procedural complications			

animal bite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
ankle fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
arthropod bite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
arthropod sting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
bite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
bone contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
burns first degree			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
chest injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
clavicle fracture			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
concussion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
contusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
craniocerebral injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
electric shock			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
epicondylitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
excoriation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
exposure during pregnancy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
exposure via father			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		

eye injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
fall			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
foot fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
foreign body in eye			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
frostbite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hand fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
heat stroke			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
joint injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
laceration			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
ligament injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
ligament rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
ligament sprain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
limb injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
meniscus injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
muscle rupture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
muscle strain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
nail injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

overdose			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
periorbital haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
post procedural complication			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
post-traumatic neck syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
procedural pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
rib fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
road traffic accident			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
scar			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
soft tissue injury			
alternative dictionary used: MedDRA 16.0			



<p>subjects affected / exposed</p> <p>0 / 180 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>thermal burn</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>0 / 180 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>tooth fracture</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>0 / 180 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>tooth injury</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>0 / 180 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>wound</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>1 / 180 (0.56%)</p> <p>occurrences (all)</p> <p>1</p>			
<p>wrist fracture</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>0 / 180 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Cardiac disorders</p> <p>angina pectoris</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>3 / 180 (1.67%)</p> <p>occurrences (all)</p> <p>3</p>			
<p>bradycardia</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>0 / 180 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>cardiac disorder</p> <p>alternative dictionary used: MedDRA 16.0</p>			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
cardiovascular disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
extrasystoles			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
palpitations			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
sinus arrhythmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sinus bradycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sinus tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
Nervous system disorders			
ageusia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
akathisia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
akinesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
apallic syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
aphasia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
autonomic nervous system imbalance			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
balance disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
burning sensation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
carpal tunnel syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		

circadian rhythm sleep disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
clumsiness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
cognitive disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
convulsion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
coordination abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
depressed level of consciousness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
disturbance in attention			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 180 (1.67%)		
occurrences (all)	3		
dizziness postural			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
drooling			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dysaesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dysarthria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dysgeusia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dyskinesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
formication			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
head discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
head titubation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

headache			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	17 / 180 (9.44%)		
occurrences (all)	38		
hypersomnia			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
hypertonia			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
hypoesthesia			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hypogeusia			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hypotonia			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
irregular sleep phase			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
lethargy			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
loss of consciousness			
alternative dictionary used:			
MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
memory impairment			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
mental impairment			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
migraine			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 180 (1.67%)		
occurrences (all)	3		
muscle contractions involuntary			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
myoclonus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
neurological symptom			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
orthostatic intolerance			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
paraesthesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		

parosmia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
poor quality sleep			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
psychomotor hyperactivity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
psychomotor skills impaired			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
restless legs syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sciatica			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
sedation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sensory disturbance			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sinus headache			
alternative dictionary used: MedDRA 16.0			



subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
somnolence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	2		
speech disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
syncope			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
tension headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
tremor			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 180 (1.67%)		
occurrences (all)	3		
trigeminal neuralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
tunnel vision			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 16.0			

<p>subjects affected / exposed</p> <p>1 / 180 (0.56%)</p> <p>occurrences (all)</p> <p>1</p>			
<p>leukopenia</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>1 / 180 (0.56%)</p> <p>occurrences (all)</p> <p>1</p>			
<p>lymphadenitis</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>0 / 180 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>lymphadenopathy</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>0 / 180 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>splenic cyst</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>0 / 180 (0.00%)</p> <p>occurrences (all)</p> <p>0</p>			
<p>Ear and labyrinth disorders</p> <p>ear discomfort</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>0 / 180 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>ear pain</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>0 / 180 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>external ear inflammation</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>0 / 180 (0.00%)</p> <p>occurrences (all)</p> <p>0</p> <p>hyperacusis</p> <p>alternative dictionary used: MedDRA 16.0</p>			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hypoacusis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
inner ear inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
motion sickness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sudden hearing loss			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
tinnitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
vertigo			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 180 (1.67%)		
occurrences (all)	4		
Eye disorders			
abnormal sensation in eye			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
accommodation disorder			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
blepharitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
blepharospasm			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
blindness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
conjunctivitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
diplopia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dry eye			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
excessive eye blinking			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
eye discharge			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

eye irritation			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
eye pain			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
glaucoma			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
iridocyclitis			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
lacrimation increased			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
miosis			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
mydriasis			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
ocular discomfort			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
ocular hyperaemia			
alternative dictionary used:			
MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
photophobia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
vision blurred			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
visual acuity reduced			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
visual impairment			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
abdominal distension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
abdominal pain lower			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 180 (1.67%)		
occurrences (all)	3		
abdominal rigidity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
aphthous stomatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
barrett's oesophagus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
breath odour			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
chapped lips			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
crohn's disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

defaecation urgency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dental caries			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
diarrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 180 (4.44%)		
occurrences (all)	10		
dry mouth			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 180 (3.33%)		
occurrences (all)	6		
dyspepsia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 180 (3.33%)		
occurrences (all)	6		
dysphagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
epigastric discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
eructation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
faeces hard			
alternative dictionary used: MedDRA 16.0			



subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
flatulence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
food poisoning			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
frequent bowel movements			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
gastric disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
gastritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 180 (3.33%)		
occurrences (all)	6		
gastrointestinal disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
gastrointestinal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

gingival bleeding			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
gingival inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
gingival pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
haematochezia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
haemorrhoidal haemorrhage			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
haemorrhoids			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
hyperchlorhydria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hypoesthesia oral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
inguinal hernia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
irritable bowel syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	9 / 180 (5.00%)		
occurrences (all)	9		
oesophagitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
oral disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
oral mucosal blistering			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
oral pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
paraesthesia oral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
periodontal disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

reflux gastritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
saliva altered			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
salivary hypersecretion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
stomatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
tooth disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
toothache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	2		
umbilical hernia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			

acne			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
alopecia			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
cold sweat			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dandruff			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dermatitis			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dermatitis acneiform			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dermatitis allergic			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
dermatitis atopic			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
dermatitis contact			
alternative dictionary used:			
MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
dry skin			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
eczema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
erythema			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
guttate psoriasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
heat rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hyperhidrosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 180 (4.44%)		
occurrences (all)	8		
hyperkeratosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hypertrichosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

lichen planus			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
neurodermatitis			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
night sweats			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
pain of skin			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
photosensitivity reaction			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
piloerection			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
pityriasis rosea			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
pruritus			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
pruritus generalised			
alternative dictionary used:			
MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
psoriasis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
rash erythematous			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
rash pruritic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
rosacea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
skin atrophy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
skin burning sensation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
skin disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		



<p>skin lesion</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>		
<p>skin odour abnormal</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>0 / 180 (0.00%)</p> <p>0</p>		
<p>solar dermatitis</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 180 (0.56%)</p> <p>1</p>		
<p>urticaria</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p>	<p>1 / 180 (0.56%)</p> <p>1</p>		
<p>Renal and urinary disorders</p> <p>bladder dysfunction</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>chromaturia</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>dysuria</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>haematuria</p> <p>alternative dictionary used: MedDRA 16.0</p> <p>subjects affected / exposed</p> <p>occurrences (all)</p> <p>incontinence</p> <p>alternative dictionary used: MedDRA 16.0</p>	<p>0 / 180 (0.00%)</p> <p>0</p> <p>0 / 180 (0.00%)</p> <p>0</p> <p>2 / 180 (1.11%)</p> <p>2</p> <p>0 / 180 (0.00%)</p> <p>0</p>		

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
micturition disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
micturition urgency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
nocturia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
pollakiuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
polyuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
renal colic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
renal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
semenuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[40]</sup>	0 / 95 (0.00%)		
occurrences (all)	0		

urethral discharge			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
urinary hesitation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
urinary incontinence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
urinary retention			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
urinary tract disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
urinary tract obstruction			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
urine abnormality			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
urine flow decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
urine odour abnormal			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
goitre			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hyperthyroidism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hypothyroidism			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
thyroid pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	8 / 180 (4.44%)		
occurrences (all)	8		
arthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 180 (3.89%)		
occurrences (all)	9		
bursitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
chondropathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
coccydynia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
compartment syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
groin pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
intervertebral disc protrusion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
joint contracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
limb discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
monarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		

muscle contracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
muscle fatigue			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
muscle spasms			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
muscle tightness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
muscular weakness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
musculoskeletal chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
musculoskeletal discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
musculoskeletal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
musculoskeletal stiffness			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
myalgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
myosclerosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
myositis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
neck pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
osteitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
pain in jaw			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

periostitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
plantar fasciitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
rotator cuff syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
scoliosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sensation of heaviness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
spinal osteoarthritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
tendon pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
tendonitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
tenosynovitis			
alternative dictionary used: MedDRA 16.0			



subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
torticollis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
acarodermatitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
acute sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
acute tonsillitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	2		
body tinea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 180 (2.78%)		
occurrences (all)	7		
candidiasis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
chlamydial cervicitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[41]</sup>	0 / 85 (0.00%)		
occurrences (all)	0		
chronic sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
cystitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 180 (2.78%)		
occurrences (all)	8		
ear infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
enteritis infectious			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
erythema migrans			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
fungus infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 180 (2.78%)		
occurrences (all)	7		

gastroenteritis norovirus			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
gastroenteritis viral			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
gastrointestinal infection			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
gastrointestinal viral infection			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
genital herpes			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
genital infection fungal			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
gingivitis			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
gonorrhoea			
alternative dictionary used:			
MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
helicobacter infection			
alternative dictionary used:			
MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
herpes simplex			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
herpes virus infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
hordeolum			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
infected bites			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
infection parasitic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	10 / 180 (5.56%)		
occurrences (all)	10		

laryngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
localised infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
lower respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
lyme disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
mycoplasma infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	22 / 180 (12.22%)		
occurrences (all)	39		
oral herpes			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
otitis media			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
peritonsillar abscess			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
pertussis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
pharyngitis streptococcal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
pharyngotonsillitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
pyelonephritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
respiratory tract infection viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		

rhinitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 180 (2.22%)		
occurrences (all)	4		
rhinovirus infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
salpingo-oophoritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[42]</sup>	0 / 85 (0.00%)		
occurrences (all)	0		
scarlet fever			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 180 (2.22%)		
occurrences (all)	4		
skin infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
subcutaneous abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
tinea pedis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
tinea versicolour			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
tonsillitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 180 (1.67%)		
occurrences (all)	4		
tooth abscess			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
tooth infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
tracheitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	2		
urethritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 180 (1.11%)		
occurrences (all)	2		
vaginal infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed <sup>[43]</sup>	0 / 85 (0.00%)		
occurrences (all)	0		



viral infection alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
viral upper respiratory tract infection alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
vulvovaginal candidiasis alternative dictionary used: MedDRA 16.0 subjects affected / exposed <sup>[44]</sup> occurrences (all)	1 / 85 (1.18%) 1		
wound infection alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
Metabolism and nutrition disorders acidosis alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
decreased appetite alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	1 / 180 (0.56%) 1		
dehydration alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
hypercholesterolaemia alternative dictionary used: MedDRA 16.0 subjects affected / exposed occurrences (all)	0 / 180 (0.00%) 0		
hyperphagia alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hypertriglyceridaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
hypoglycaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
increased appetite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
polydipsia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
tetany			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
type 2 diabetes mellitus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		
vitamin b12 deficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 180 (0.56%)		
occurrences (all)	1		
vitamin d deficiency			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 180 (0.00%)		
occurrences (all)	0		



[33] - The number of subjects exposed to this adverse event is less than the total number of subjects

exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[34] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[35] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[36] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[37] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[38] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[39] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[40] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[41] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[42] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[43] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

[44] - The number of subjects exposed to this adverse event is less than the total number of subjects exposed for the reporting group. These numbers are expected to be equal.

Justification: This event is gender specific, only occurring in male or female subjects. The number of subjects exposed has been adjusted accordingly

## **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