Clinical trial results:
A Double-Blind, Efficacy and Safety Study of Duloxetine Versus Placebo in the Treatment of Children and Adolescents With Major Depressive Disorder

Summary

EudraCT number	2017-001598-18
Trial protocol	Outside EU/EEA
Global end of trial date	05 September 2011

Results information

Result version number	v1 (current)
This version publication date	22 December 2021
First version publication date	22 December 2021

Trial information

Trial identification

Sponsor protocol code	F1JMCHMCL

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00849693
WHO universal trial number (UTN)	-

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 Limited, 1 877-CTLilly, EU_Lilly_Clinical_Trials@lilly.com
Scientific contact	Available Mon-Fri 9 AM - 5 PM EST, Eli Lilly and Company Limited, 1 877-285-4559, EU_Lilly_Clinical_Trials@lilly.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 September 2011
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 September 2011
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to assess whether duloxetine is superior to placebo in the treatment of children and adolescents with major depressive disorder (MDD).

Protection of trial subjects:

This study was conducted in accordance with International Conference on Harmonization (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 March 2009
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	United States: 364
Country: Number of subjects enrolled	Mexico: 74
Country: Number of subjects enrolled	Canada: 24
Country: Number of subjects enrolled	Argentina: 1
Worldwide total number of subjects	463
EEA total number of subjects	0

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	463
Adults (18-64 years)	0
From 65 to 84 years	0

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study consisted of a 10-week acute treatment phase, and a 6-month extension phase.

Pre-assignment

Screening details:

Not Applicable

Period 1

Period 1 title	Acute Treatment Phase
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Duloxetine 60 mg

Arm description:

Participants were treated with Duloxetine 60 milligram (mg) orally, once daily for 10 weeks during acute treatment phase.

Arm type	Experimental
Investigational medicinal product name	Duloxetine
Investigational medicinal product code	
Other name	LY248686, Cymbalta
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Duloxetine 60 mg, orally, once daily for 10 weeks.

Arm title	Duloxetine 30 mg

Arm description:

Duloxetine 30 mg, orally, once daily for 10 weeks.

Arm type	Experimental
Investigational medicinal product name	Duloxetine
Investigational medicinal product code	
Other name	LY248686, Cymbalta
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Duloxetine 30 mg, orally, once daily for 10 weeks.

Arm title	Fluoxetine 20 mg

Arm description:

Participants were treated with Fluoxetine 20 mg orally, once daily for 10 weeks during acute treatment phase.

Arm type	Experimental

Investigational medicinal product name	Fluoxetine
Investigational medicinal product code	
Other name	LY110140; Prozac
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Participants were treated with Fluoxetine 20 mg orally, once daily for 10 weeks.

Arm title	Placebo

Arm description:

Participants were treated with placebo orally, once daily for 10 weeks during acute treatment phase.

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

Dosage and administration details:

Participants were treated with placebo orally, once daily for 10 weeks.

Number of subjects in period 1	Duloxetine 60 mg	Duloxetine 30 mg	Fluoxetine 20 mg
Started	108	116	117
Completed	75	81	84
Not completed	33	35	33
Consent withdrawn by subject	5	5	3
Physician decision	2	1	2
Adverse event, non-fatal	12	7	6
Sponsor Decision	-	-	1
Lost to follow-up	5	8	11
Parent or caregiver decision	7	6	7
Protocol deviation	1	5	2
Lack of efficacy	1	3	1

Number of subjects in period 1	Placebo
Started	122
Completed	85
Not completed	37
Consent withdrawn by subject	8
Physician decision	1
Adverse event, non-fatal	4
Sponsor Decision	-
Lost to follow-up	9
Parent or caregiver decision	7

Protocol deviation	6
Lack of efficacy	2

Period 2

Period 2 title	Extension Phase
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
Arm title	Duloxetine 60-120 mg

Arm description:

Participants received Duloxetine 60-120 mg orally, once daily for 6 months during extension phase.

Arm type	Experimental
Investigational medicinal product name	Duloxetine
Investigational medicinal product code	
Other name	LY248686, Cymbalta
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Duloxetine 60-120 mg orally, once daily for 6 months.

Arm title	Duloxetine 60-120 mg

Arm description:

Participants received Duloxetine 60-120 mg orally, once daily for 6 months during extension phase

Arm type	Experimental
Investigational medicinal product name	Duloxetine
Investigational medicinal product code	
Other name	LY248686, Cymbalta
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Duloxetine 60-120 mg orally, once daily for 6 months.

Arm title	Fluoxetine 20-40 mg

Arm description:

Participants received Fluoxetine 20-40 mg orally, once daily for 6 months during extension phase.

Arm type	Experimental
Investigational medicinal product name	Fluoxetine
Investigational medicinal product code	
Other name	LY110140; Prozac
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Fluoxetine 20-40 mg orally, once daily for 6 months.

Arm title	Duloxetine 60-120 mg

Arm description:
Participants received Duloxetine 60-120 mg orally, once daily for 6 months during extension phase.

Arm type	Experimental
Investigational medicinal product name	Duloxetine
Investigational medicinal product code	
Other name	LY248686, Cymbalta
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:
Duloxetine 60-120 mg orally, once daily for 6 months.

Number of subjects in period 2[1]	Duloxetine 60-120 mg	Duloxetine 60-120 mg	Fluoxetine 20-40 mg
Started	73	80	84
Completed	43	50	49
Not completed	30	30	35
Consent withdrawn by subject	6	9	10
Physician decision	1	1	2
Adverse event, non-fatal	4	6	3
Sponsor Decision	1	-	-
Lost to follow-up	7	5	6
Parent or caregiver decision	9	4	10
Lack of efficacy	2	2	2
Protocol deviation	-	3	2

Number of subjects in period 2[1]	Duloxetine 60-120 mg
Started	82
Completed	44
Not completed	38
Consent withdrawn by subject	15
Physician decision	-
Adverse event, non-fatal	7
Sponsor Decision	1
Lost to follow-up	6
Parent or caregiver decision	5

Lack of efficacy	1
Protocol deviation	3

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: Few participants decided not to enter Extension phase.

Baseline characteristics

Reporting groups	
Reporting group title	Duloxetine 60 mg
Reporting group description:	
Participants were treated with Duloxetine 60 milligram (mg) orally, once daily for 10 weeks during acute treatment phase.	
Reporting group title	Duloxetine 30 mg
Reporting group description:	
Duloxetine 30 mg, orally, once daily for 10 weeks.	
Reporting group title	Fluoxetine 20 mg
Reporting group description:	
Participants were treated with Fluoxetine 20 mg orally, once daily for 10 weeks during acute treatment phase.	
Reporting group title	Placebo
Reporting group description:	
Participants were treated with placebo orally, once daily for 10 weeks during acute treatment phase.	

Reporting group values	Duloxetine 60 mg	Duloxetine 30 mg	Fluoxetine 20 mg
Number of subjects	108	116	117
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	12.92	12.86	13.04
standard deviation	± 2.925	± 2.904	± 3.205
Gender categorical Units: Subjects			
Female	60	47	61
Male	48	69	56
Race and Ethnicity Units: Subjects			
American Indian or Alaska Native	15	23	16
Asian	0	1	1
Black or African American	27	21	21
Native Hawaiian or Other Pacific Islander	0	1	0
White	54	61	67
Multiracial	6	6	9

Not Provided	6	3	3
Region of Enrollment Units: Subjects			
United States	87	86	93
Mexico	16	25	16
Canada	5	5	7
Argentina	0	0	1
Children's Depression Rating Scale-Revised (CDRS-R) Total Score			
CDRS-R Total score measure the presence and severity of depression in children. The scale consists of 17 items scored on a 1-to-5- or 1-to-7-point scale. A rating of 1 indicates normal functioning. Total scores range from 17 to 113. In general, scores below 20 indicate an absence of depression, scores of 20 to 30 indicate borderline depression, and scores of 40 to 60 indicate moderate depression.			
Units: Units on a Scale			
arithmetic mean	59.3	59.8	57.9
standard deviation	± 10.87	± 11.00	± 10.11

Reporting group values	Placebo	Total	
Number of subjects	122	463	
Age categorical Units: Subjects			
In utero		0	
Preterm newborn infants (gestational age < 37 wks)		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)		0	
From 65-84 years		0	
85 years and over		0	
Age continuous Units: years			
arithmetic mean	13.09		
standard deviation	± 2.895	-	
Gender categorical Units: Subjects			
Female	69	237	
Male	53	226	
Race and Ethnicity Units: Subjects			
American Indian or Alaska Native	19	73	
Asian	1	3	
Black or African American	24	93	
Native Hawaiian or Other Pacific Islander	0	1	
White	62	244	
Multiracial	13	34	
Not Provided	3	15	
Region of Enrollment Units: Subjects			
United States	98	364	

Mexico	17	74	
Canada	7	24	
Argentina	0	1	

Children's Depression Rating Scale-Revised (CDRS-R) Total Score			
CDRS-R Total score measure the presence and severity of depression in children. The scale consists of 17 items scored on a 1-to-5- or 1-to-7-point scale. A rating of 1 indicates normal functioning. Total scores range from 17 to 113. In general, scores below 20 indicate an absence of depression, scores of 20 to 30 indicate borderline depression, and scores of 40 to 60 indicate moderate depression.			
Units: Units on a Scale			
arithmetic mean	58.2		
standard deviation	± 9.35	-	

End points

End points reporting groups

Reporting group title	Duloxetine 60 mg
Reporting group description:	
Participants were treated with Duloxetine 60 milligram (mg) orally, once daily for 10 weeks during acute treatment phase.	
Reporting group title	Duloxetine 30 mg
Reporting group description:	
Duloxetine 30 mg, orally, once daily for 10 weeks.	
Reporting group title	Fluoxetine 20 mg
Reporting group description:	
Participants were treated with Fluoxetine 20 mg orally, once daily for 10 weeks during acute treatment phase.	
Reporting group title	Placebo
Reporting group description:	
Participants were treated with placebo orally, once daily for 10 weeks during acute treatment phase.	
Reporting group title	Duloxetine 60-120 mg
Reporting group description:	
Participants received Duloxetine 60-120 mg orally, once daily for 6 months during extension phase.	
Reporting group title	Duloxetine 60-120 mg
Reporting group description:	
Participants received Duloxetine 60-120 mg orally, once daily for 6 months during extension phase	
Reporting group title	Fluoxetine 20-40 mg
Reporting group description:	
Participants received Fluoxetine 20-40 mg orally, once daily for 6 months during extension phase.	
Reporting group title	Duloxetine 60-120 mg
Reporting group description:	
Participants received Duloxetine 60-120 mg orally, once daily for 6 months during extension phase.	

Primary: Change From Baseline in Children's Depression Rating Scale-Revised (CDRS-R) Total Score at Week 10 Endpoint

End point title	Change From Baseline in Children's Depression Rating Scale-Revised (CDRS-R) Total Score at Week 10 Endpoint[1]

End point description:

CDRS-R Total score measure the presence and severity of depression in children. The scale consists of 17 items scored on a 1-to-5- or 1-to-7-point scale. A rating of 1 indicates normal functioning. Total scores range from 17 to 113. In general, scores below 20 indicate an absence of depression, scores of 20 to 30 indicate borderline depression, and scores of 40 to 60 indicate moderate depression. Least Square (LS) means are adjusted for baseline, pooled investigator, age category, visit, treatment, treatment*visit, age category*visit and baseline*visit.

Analysis Population Description: Participants with both a baseline and at least one post-baseline value.

End point type	Primary

End point timeframe:

Baseline, Week 10

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No inferential statistics planned for this outcome.

End point values	Duloxetine 60 mg	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	105	117		
Units: Units on a Scale				
least squares mean (standard error)	-23.9 (± 1.30)	-21.6 (± 1.27)		

Statistical analyses

Statistical analysis title	CDRS-R
Comparison groups	Duloxetine 60 mg v Placebo
Number of subjects included in analysis	222
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.193
Method	Mixed models analysis

Secondary: Change From Week 10 in Children's Depression Rating Scale-Revised (CDRS-R) Total Score at Week 36 Endpoint

End point title	Change From Week 10 in Children's Depression Rating Scale-Revised (CDRS-R) Total Score at Week 36 Endpoint

End point description:

CDRS-R Total score measure the presence and severity of depression in children. The scale consists of 17 items scored on a 1-to-5- or 1-to-7-point scale. A rating of 1 indicates normal functioning. Total scores range from 17 to 113. In general, scores below 20 indicate an absence of depression, scores of 20 to 30 indicate borderline depression, and scores of 40 to 60 indicate moderate depression. LS means are adjusted for baseline, pooled investigator, age category, visit, age category*visit and baseline*visit. APD: Participants with value during treatment phase and at least one post-Week 10 value.

End point type	Secondary

End point timeframe:

Week 10, Week 36

End point values	Duloxetine 60-120 mg	Duloxetine 60-120 mg	Fluoxetine 20-40 mg	Duloxetine 60-120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	78	80	79
Units: Units on a Scale				
least squares mean (standard error)	-7.8 (± 1.04)	-7.4 (± 1.23)	-10.0 (± 1.17)	-9.0 (± 1.84)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Children's Depression Rating Scale-Revised (CDRS-R) Total Score at Week 10 Endpoint

End point title	Change From Baseline in Children's Depression Rating Scale-Revised (CDRS-R) Total Score at Week 10 Endpoint[2]

End point description:

CDRS-R Total score measure the presence and severity of depression in children. The scale consists of 17 items scored on a 1-to-5- or 1-to-7-point scale. A rating of 1 indicates normal functioning. Total scores range from 17 to 113. In general, scores below 20 indicate an absence of depression, scores of 20 to 30 indicate borderline depression, and scores of 40 to 60 indicate moderate depression. Least Square (LS) means are adjusted for baseline, pooled investigator, age category, visit, treatment, treatment*visit, age category*visit and baseline*visit.
APD: Participants with both a baseline and at least one post-baseline value.

End point type	Secondary

End point timeframe:

Baseline, Week 10

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No inferential statistics planned for this outcome.

End point values	Duloxetine 30 mg	Fluoxetine 20 mg	Placebo	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	112	117	
Units: units on a scale				
least squares mean (standard error)	-24.6 (± 1.29)	-22.6 (± 1.27)	-21.6 (± 1.27)	

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Children's Depression Rating Scale-Revised (CDRS-R) Subscale Score at Week 10 Endpoint

End point title	Change From Baseline in Children's Depression Rating Scale-Revised (CDRS-R) Subscale Score at Week 10 Endpoint

End point description:

CDRS-R Subscale scores include Mood (Sum of items 8, 11, 14, 15), Somatic (Sum of items 4-7, 16, 17), Subjective (Sum of items 9, 10, 12, 13) and Behavior (Sum of items 1-3). Mood and Subjective subscale scores range from 4 to 28; Somatic subscale scores range from 6 to 36; Behavior subscale scores range from 3 to 21. Higher score indicates greater severity of disease. LS means are adjusted for baseline, pooled investigator, age category, visit, treatment, treatment*visit, age category*visit and baseline*visit.
APD: Participants with both a baseline and at least one post-baseline values.

End point type	Secondary

End point timeframe:

Baseline, Week 10

End point values	Duloxetine 60 mg	Duloxetine 30 mg	Fluoxetine 20 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	105	114	112	117
Units: units on a scale				
least squares mean (standard error)				
Mood	-7.1 (± 0.44)	-7.2 (± 0.44)	-6.6 (± 0.43)	-6.4 (± 0.43)
Somatic	-7.6 (± 0.48)	-7.9 (± 0.48)	-7.1 (± 0.47)	-6.4 (± 0.47)
Subjective	-3.6 (± 0.26)	-4.0 (± 0.26)	-3.5 (± 0.26)	-3.6 (± 0.26)
Behavior	-5.8 (± 0.36)	-5.6 (± 0.36)	-5.6 (± 0.35)	-5.4 (± 0.35)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Week 10 in Children's Depression Rating Scale-Revised (CDRS-R) Subscale Score at Week 36 Endpoint

End point title	Change From Week 10 in Children's Depression Rating Scale-Revised (CDRS-R) Subscale Score at Week 36 Endpoint

End point description:

CDRS-R Subscale scores include Mood (Sum of items 8, 11, 14, 15), Somatic (Sum of items 4-7, 16, 17), Subjective (Sum of items 9, 10, 12, 13) and Behavior (Sum of items 1-3). Mood and Subjective subscale scores range from 4 to 28; Somatic subscale scores range from 6 to 36; Behavior subscale scores range from 3 to 21. Higher score indicates greater severity of disease. LS means are adjusted for baseline, pooled investigator, age category, visit, age category*visit and baseline*visit.

APD: Participants with value during treatment phase and at least one post-Week 10 value.

End point type	Secondary

End point timeframe:

Week 10, Week 36

End point values	Duloxetine 60-120 mg	Duloxetine 60-120 mg	Fluoxetine 20-40 mg	Duloxetine 60-120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	70	78	80	79
Units: units on a scale				
least squares mean (standard error)				
Mood	-1.9 (± 0.43)	-1.9 (± 0.42)	-2.4 (± 0.44)	-2.3 (± 0.59)
Somatic	-2.8 (± 0.41)	-2.4 (± 0.52)	-4.0 (± 0.47)	-3.2 (± 0.66)
Subjective	-1.2 (± 0.25)	-1.3 (± 0.19)	-1.5 (± 0.21)	-1.0 (± 0.32)
Behavior	-2.1 (± 0.30)	-1.8 (± 0.32)	-2.7 (± 0.28)	-2.4 (± 0.50)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Clinical Global Impressions of Severity (CGI-Severity) Scale at Week 10 Endpoint

End point title	Change From Baseline in Clinical Global Impressions of Severity (CGI-Severity) Scale at Week 10 Endpoint

End point description:

CGI-Severity evaluates the severity of illness at the time of assessment. The score ranges from 1 (normal, not at all ill) to 7 (among the most extremely ill patients). LS means are adjusted for baseline, pooled investigator, age category, visit, treatment, treatment*visit, age category*visit and baseline*visit.

APD: Participants with both a baseline and at least one post-baseline value.

End point type	Secondary

End point timeframe:

Baseline, Week 10

End point values	Duloxetine 60 mg	Duloxetine 30 mg	Fluoxetine 20 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	105	114	112	117
Units: Units on a Scale				
least squares mean (standard error)	-1.5 (± 0.12)	-1.5 (± 0.12)	-1.4 (± 0.11)	-1.4 (± 0.11)

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Week 10 in Clinical Global Impressions of Severity (CGI-Severity) Scale at Week 36 Endpoint

End point title	Change From Week 10 in Clinical Global Impressions of Severity (CGI-Severity) Scale at Week 36 Endpoint

End point description:

CGI-Severity evaluates the severity of illness at the time of assessment. The score ranges from 1 (normal, not at all ill) to 7 (among the most extremely ill patients). LS means are adjusted for baseline, pooled investigator, age category, visit, age category*visit and baseline*visit.

APD: Participants with value during treatment phase and at least one post-Week 10 value.

End point type	Secondary

End point timeframe:

Week 10, Week 36

End point values	Duloxetine 60-120 mg	Duloxetine 60-120 mg	Fluoxetine 20-40 mg	Duloxetine 60-120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	78	81	79
Units: units on a scale				
least squares mean (standard error)	-1.1 (± 0.13)	-0.9 (± 0.16)	-1.3 (± 0.12)	-1.0 (± 0.13)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Suicidal Ideation or Suicidal Behavior Baseline Through Week 10

End point title	Number of Participants With Suicidal Ideation or Suicidal Behavior Baseline Through Week 10

End point description:

Columbia Suicide Rating Scale (C-SSRS) captures occurrence, severity, and frequency of suicide-related thoughts and behaviors. Suicidal behavior: a "yes" answer to any of 5 suicidal behavior questions: preparatory acts or behavior, aborted attempt, interrupted attempt, actual attempt, and completed suicide. Suicidal ideation: a "yes" answer to any one of 5 suicidal ideation questions: wish to be dead, and 4 different categories of active suicidal ideation. Treatment Emergent Suicidal Ideation is worsening or new occurrence of events during treatment compared to lead-in baseline (Week -1 to 0).

APD: Participants with a baseline and at least one post-baseline C-SSRS suicidal ideation or suicidal behavior score and who are at risk for treatment emergent suicidal ideation or behavior.

End point type	Secondary

End point timeframe:

Baseline through Week 10

End point values	Duloxetine 60 mg	Duloxetine 30 mg	Fluoxetine 20 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	105	115	112	117
Units: Participants				
number (not applicable)				
Suicidal Ideation	16	11	13	15
Suicidal Behavior	0	0	1	1
Treatment Emergent Suicidal Ideation	7	6	9	11

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Suicidal Ideation or Suicidal Behavior Week 10 Through Week 36

End point title	Number of Participants With Suicidal Ideation or Suicidal Behavior Week 10 Through Week 36

End point description:

Columbia Suicide Rating Scale (C-SSRS) captures occurrence, severity, and frequency of suicide-related thoughts and behaviors. Suicidal behavior: a "yes" answer to any of 5 suicidal behavior questions: preparatory acts or behavior, aborted attempt, interrupted attempt, actual attempt, and completed suicide. Suicidal ideation: a "yes" answer to any one of 5 suicidal ideation questions: wish to be dead, and 4 different categories of active suicidal ideation. Treatment Emergent Suicidal Ideation is worsening or new occurrence of events during treatment compared to lead-in baseline (Week 7-10).

APD: Participants with a baseline and at least one post-baseline C-SSRS suicidal ideation or suicidal behavior score and who are at risk for treatment emergent suicidal ideation or behavior.

End point type	Secondary

End point timeframe:

Week 10 through Week 36

End point values	Duloxetine 60-120 mg	Duloxetine 60-120 mg	Fluoxetine 20-40 mg	Duloxetine 60-120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	71	78	80	79
Units: Participants				
number (not applicable)				
Suicidal Ideation	6	12	8	8
Suicidal Behavior	2	3	0	1
Treatment Emergent Suicidal Ideation	5	8	7	6

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Potentially Clinically Significant Hepatic Laboratory Results Any Time Baseline Through Week 10

End point title	Number of Participants With Potentially Clinically Significant Hepatic Laboratory Results Any Time Baseline Through Week 10

End point description:

Total number of participants with any abnormal post-baseline value, based on all values at scheduled and unscheduled visits. Potentially clinically significant hepatic laboratory results at any time are defined as alanine transaminase (ALT) ≥3 x upper limit of normal (ULN), ALT ≥5 x ULN and ALT ≥10 x ULN, as well as ALT ≥3 x ULN and Total Bilirubin ≥2 x ULN.

APD: Participants with normal ALT value (ALT<1 x ULN) at last non-missing baseline visit and at least one non-missing post-baseline value.

End point type	Secondary

End point timeframe:

Baseline through Week 10

End point values	Duloxetine 60 mg	Duloxetine 30 mg	Fluoxetine 20 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	95	98	102	100
Units: Participants				
number (not applicable)				
ALT≥3 x ULN	0	0	0	0
ALT≥5 x ULN	0	0	0	0
ALT≥10 x ULN	0	0	0	0
ALT≥3 x ULN and Total Bilirubin≥2 x ULN	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With Potentially Clinically Significant Hepatic Laboratory Results Any Time Week 10 Through Week 36

End point title	Number of Participants With Potentially Clinically Significant Hepatic Laboratory Results Any Time Week 10 Through Week 36

End point description:

Total number of participants with any abnormal post-baseline value, based on all values at scheduled and unscheduled visits. Potentially clinically significant hepatic laboratory results at any time are defined as ALT ≥3 x ULN, ALT ≥5 x ULN and ALT ≥10 x ULN, as well as ALT≥3 x ULN and Total Bilirubin ≥2 x ULN.

End point type	Secondary

End point timeframe:

Week 10 through Week 36

End point values	Duloxetine 60-120 mg	Duloxetine 60-120 mg	Fluoxetine 20-40 mg	Duloxetine 60-120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	69	69	77	73
Units: Participants				
number (not applicable)				
ALT≥3 x ULN	0	0	0	0
ALT≥5 x ULN	0	0	0	0
ALT≥10 x ULN	0	0	0	0
ALT≥3 x ULN and Total Bilirubin≥2 x ULN	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Potentially Clinically Significant (PCS) Changes in Systolic Blood Pressure (BP), Diastolic BP, Pulse, and Weight Any Time Baseline Through Week 10

End point title	Percentage of Participants With Potentially Clinically Significant (PCS) Changes in Systolic Blood Pressure (BP), Diastolic BP, Pulse, and Weight Any Time Baseline Through Week 10

End point description:

PCS increase in systolic and diastolic BP was defined as increase of ≥5 millimeter mercury (mm Hg) from baseline (BL) high value to a value above the 95th percentile at post-BL; PCS increase of pulse was defined as >140 and increase of ≥15 from BL high value for age 7-11 and >120 and increase of ≥15 from BL high value for age 12-17; PCS decrease of pulse was defined as <60 and a decrease of ≥25 from BL low value for age 7-11 and <50 and a decrease of ≥15 from BL low value for age 12-17; PCS decrease of weight was defined as decrease of at least 3.5% from BL low value.

APD: Participants with normal baseline value and at least one post-baseline value, and who were at risk for the specific PCS criteria.

End point type	Secondary

End point timeframe:

Baseline through Week 10

End point values	Duloxetine 60 mg	Duloxetine 30 mg	Fluoxetine 20 mg	Placebo
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	108[3]	116[4]	117[5]	122[6]
Units: percentage of participants				
number (not applicable)				
Diastolic BP Increase	11.8	7.0	10.1	4.5
Systolic BP Increase	9.1	12.6	12.9	10.2
Pulse Decrease	0	0	0	0
Pulse Increase	0	0	0	0
Weight Decrease	13.3	8.8	11.6	5.1

Notes:

[3] - Diastolic BP (93), Systolic BP (88), Pulse Decrease(100), Pulse Increase (105), Weight Decrease (105)
[4] - Diastolic BP(100), Systolic BP (95), Pulse Decrease(108), Pulse Increase (114), Weight Decrease (114)
[5] - Diastolic BP(99), Systolic BP (93), Pulse Decrease(108), Pulse Increase (112), Weight Decrease (112)
[6] - Diastolic BP(110), Systolic BP (98), Pulse Decrease(112), Pulse Increase (117), Weight Decrease (117)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Potentially Clinically Significant (PCS) Changes in Systolic Blood Pressure (BP), Diastolic BP, Pulse, and Weight Any Time Week 10 Through Week 36

End point title	Percentage of Participants With Potentially Clinically Significant (PCS) Changes in Systolic Blood Pressure (BP), Diastolic BP, Pulse, and Weight Any Time Week 10 Through Week 36

End point description:

PCS increase in systolic and diastolic BP was defined as increase of ≥5 mm Hg from baseline (BL) high value to a value above the 95th percentile at post-BL; PCS increase of pulse was defined as >140 and

increase of ≥15 from BL high value for age 7-11 and >120 and increase of ≥15 from BL high value for age 12-17; PCS decrease of pulse was defined as <60 and a decrease of ≥25 from BL low value for age 7-11 and <50 and a decrease of ≥15 from BL low value for age 12-17; PCS decrease of weight was defined as decrease of at least 3.5% from BL low value.

APD: Participates with normal value before week 10 and at least one non-missing post-Week 10 value, and who are at risk for the specific PCS criteria.

End point type	Secondary

End point timeframe:

Week 10 through Week 36

End point values	Duloxetine 60-120 mg	Duloxetine 60-120 mg	Fluoxetine 20-40 mg	Duloxetine 60-120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	73[7]	80[8]	84[9]	82[10]
Units: Percentage of participants				
number (not applicable)				
Diastolic BP Increase	14.5	4.6	20.3	11.6
Systolic BP Increase	9.4	6.5	7.0	10.5
Pulse Decrease	0	0	0	0
Pulse Increase	1.4	0	0	1.3
Weight Decrease	2.8	9.0	3.7	13.9

Notes:

[7] - Diastolic BP (55), Systolic BP (53), Pulse Decrease (68), Pulse Increase (71), Weight Decrease (71)

[8] - Diastolic BP (65), Systolic BP (62), Pulse Decrease (75), Pulse Increase (78), Weight Decrease (78)

[9] - Diastolic BP (64), Systolic BP (57), Pulse Decrease (76), Pulse Increase (81), Weight Decrease (81)

[10] - Diastolic BP (69), Systolic BP (57), Pulse Decrease (73), Pulse Increase (79), Weight Decrease (79)

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:	
F1J-MC-HMCL	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	14.0

Reporting groups	
Reporting group title	Placebo_Acute
Reporting group description: -	
Reporting group title	Duloxetine 60 mg_Acute
Reporting group description: -	
Reporting group title	Fluoxetine_Acute
Reporting group description: -	
Reporting group title	Duloxetine 30 mg_Acute
Reporting group description: -	
Reporting group title	Placebo/Duloxetine 60-120 mg_Extension
Reporting group description: -	
Reporting group title	Fluoxetine_Extension
Reporting group description: -	
Reporting group title	Duloxetine 60/60-120 mg_Extension
Reporting group description: -	
Reporting group title	Duloxetine 30/60-120 mg_Extension
Reporting group description: -	

Serious adverse events	Placebo_Acute	Duloxetine 60 mg_Acute	Fluoxetine_Acute
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 122 (1.64%)	4 / 108 (3.70%)	6 / 117 (5.13%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
intentional overdose			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	2 / 108 (1.85%)	1 / 117 (0.85%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
road traffic accident			
alternative dictionary used:			

MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (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
wound			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (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
Nervous system disorders			
epilepsy			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (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
somnolence			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
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			
irritable bowel syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
stevens-johnson syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (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
Psychiatric disorders			
abnormal behaviour			

alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
aggression			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	2 / 117 (1.71%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
depression			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (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
depressive symptom			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (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			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (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
homicidal ideation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (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
self injurious behaviour			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (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
suicidal ideation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	2 / 117 (1.71%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
suicide attempt			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
tuberculosis of peripheral lymph nodes			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Duloxetine 30 mg_Acute	Placebo/Duloxetine 60-120 mg_Extension	Fluoxetine_Extension
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 116 (1.72%)	4 / 82 (4.88%)	1 / 84 (1.19%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
intentional overdose			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (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
road traffic accident			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (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
wound			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (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
Nervous system disorders			
epilepsy			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (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
somnolence			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
irritable bowel syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (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
Skin and subcutaneous tissue disorders			
stevens-johnson syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (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
Psychiatric disorders			
abnormal behaviour			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (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
aggression			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (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
depression			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (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
depressive symptom			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (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
hallucination			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (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
homicidal ideation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (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
self injurious behaviour			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (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

suicidal ideation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (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
suicide attempt			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (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
Infections and infestations			
tuberculosis of peripheral lymph nodes			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (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

Serious adverse events	Duloxetine 60/60-120 mg_Extension	Duloxetine 30/60-120 mg_Extension	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 73 (4.11%)	2 / 81 (2.47%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
intentional overdose			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
road traffic accident			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
wound			

alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
epilepsy			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
somnolence			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
irritable bowel syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
stevens-johnson syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
abnormal behaviour			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
aggression			

alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
depression			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
depressive symptom			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hallucination			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
homicidal ideation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
self injurious behaviour			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
suicidal ideation			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
suicide attempt			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	2 / 81 (2.47%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
tuberculosis of peripheral lymph nodes			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo_Acute	Duloxetine 60 mg_Acute	Fluoxetine_Acute
Total subjects affected by non-serious adverse events			
subjects affected / exposed	71 / 122 (58.20%)	76 / 108 (70.37%)	69 / 117 (58.97%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
flushing			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
hot flush			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
Surgical and medical procedures			
cholecystectomy			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
influenza immunisation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
chest pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
chills			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
discomfort			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
energy increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
face oedema			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
facial pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	4 / 122 (3.28%)	5 / 108 (4.63%)	4 / 117 (3.42%)
occurrences (all)	4	5	4
feeling abnormal			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
feeling cold			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
feeling hot			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
feeling jittery			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
feeling of body temperature change			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
hyperthermia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0

influenza like illness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
irritability			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 122 (1.64%)	3 / 108 (2.78%)	0 / 117 (0.00%)
occurrences (all)	2	3	0
medical device complication			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
non-cardiac chest pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	1	0	1
pyrexia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	4 / 122 (3.28%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	4	1	0
sluggishness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 122 (1.64%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	2	0	0
therapeutic response unexpected			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			

allergy to animal			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
hypersensitivity			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	3 / 117 (2.56%)
occurrences (all)	0	0	3
seasonal allergy			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
Social circumstances			
menarche			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[1]	1 / 69 (1.45%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
victim of sexual abuse			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[2]	1 / 69 (1.45%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	1	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[3]	3 / 69 (4.35%)	2 / 60 (3.33%)	1 / 61 (1.64%)
occurrences (all)	3	3	2
menstruation delayed			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[4]	0 / 69 (0.00%)	0 / 60 (0.00%)	0 / 61 (0.00%)
occurrences (all)	0	0	0
menstruation irregular			

alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[5]	0 / 69 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
pruritus genital			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
cough			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	3 / 122 (2.46%)	2 / 108 (1.85%)	2 / 117 (1.71%)
occurrences (all)	3	2	2
epistaxis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	3 / 117 (2.56%)
occurrences (all)	1	0	3
nasal congestion			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	2 / 117 (1.71%)
occurrences (all)	1	0	2
oropharyngeal pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	3 / 122 (2.46%)	3 / 108 (2.78%)	6 / 117 (5.13%)
occurrences (all)	3	3	6
rhinitis allergic			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	1	1	0
rhinitis seasonal			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	1 / 117 (0.85%)
occurrences (all)	0	1	1
sinus congestion			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	1	1	0
sneezing			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
snoring			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
yawning			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
abnormal behaviour			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	2 / 117 (1.71%)
occurrences (all)	0	0	3
abnormal dreams			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	2 / 117 (1.71%)
occurrences (all)	0	1	2
aggression			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
agitation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
anger			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
anorexia nervosa			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
anxiety			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	1 / 108 (0.93%)	1 / 117 (0.85%)
occurrences (all)	1	1	1
bipolar disorder			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
confusional state			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
depression			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0

derealisation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
emotional disorder			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
hallucination, auditory			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
hallucination, visual			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
hallucinations, mixed			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
hypomania			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
impulsive behaviour			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
inappropriate affect			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
initial insomnia			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	1 / 122 (0.82%)	2 / 108 (1.85%)	1 / 117 (0.85%)
occurrences (all)	1	2	1
insomnia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	4 / 122 (3.28%)	3 / 108 (2.78%)	5 / 117 (4.27%)
occurrences (all)	4	3	5
intentional drug misuse			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
intentional self-injury			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	2 / 108 (1.85%)	2 / 117 (1.71%)
occurrences (all)	1	3	2
middle insomnia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
mood swings			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	2	0	0
nervousness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
nightmare			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	2 / 108 (1.85%)	0 / 117 (0.00%)
occurrences (all)	0	2	0
pyromania			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0

restlessness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	2 / 117 (1.71%)
occurrences (all)	1	0	2
sleep disorder			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 122 (1.64%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	2	0	0
somnambulism			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
suicidal ideation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 122 (1.64%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	2	0	0
tachyphrenia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
tearfulness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
terminal insomnia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
tic			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
Investigations			

blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
blood uric acid increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
heart rate increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
human papilloma virus test positive			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
lymph node palpable			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
weight increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			

accidental exposure			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
accidental overdose			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
animal bite			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
concussion			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	1	1	0
excoriation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
facial bones fracture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
fall			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
hand fracture			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
head injury			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
inappropriate schedule of drug administration			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
incorrect dose administered			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	3 / 117 (2.56%)
occurrences (all)	0	1	3
intentional overdose			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
joint dislocation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
joint injury			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
joint sprain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	1 / 108 (0.93%)	1 / 117 (0.85%)
occurrences (all)	1	1	1
laceration			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1

limb injury			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
muscle rupture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
periorbital haematoma			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
post concussion syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
procedural dizziness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
procedural pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
road traffic accident			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
skeletal injury			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
stress fracture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
sunburn			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
thermal burn			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	1 / 117 (0.85%)
occurrences (all)	0	1	1
upper limb fracture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
wrist fracture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
palpitations			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
aphasia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
cerebral disorder			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
crying			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
delayed sleep phase			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
disturbance in attention			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
dizziness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	8 / 122 (6.56%)	9 / 108 (8.33%)	5 / 117 (4.27%)
occurrences (all)	8	9	5
headache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	16 / 122 (13.11%)	19 / 108 (17.59%)	22 / 117 (18.80%)
occurrences (all)	19	22	26
hyperreflexia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
hypersomnia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
memory impairment			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0

migraine			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
paraesthesia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
poor quality sleep			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
post-traumatic headache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
psychomotor hyperactivity			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	1 / 117 (0.85%)
occurrences (all)	0	1	1
sedation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	5 / 108 (4.63%)	0 / 117 (0.00%)
occurrences (all)	0	5	0
sensory disturbance			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
sinus headache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
somnolence			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	6 / 122 (4.92%)	11 / 108 (10.19%)	4 / 117 (3.42%)
occurrences (all)	6	11	4
syncope			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
tension headache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	1	0	1
tremor			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
iron deficiency anaemia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
thrombocytosis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
motion sickness			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
tinnitus			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	2 / 117 (1.71%)
occurrences (all)	0	0	2
vertigo			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	2 / 117 (1.71%)
occurrences (all)	0	0	2
Eye disorders			
astigmatism			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
blepharospasm			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
conjunctivitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
conjunctivitis allergic			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
eye pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
hypermetropia			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
mydriasis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
myopia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
vision blurred			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	1 / 117 (0.85%)
occurrences (all)	0	1	1
abdominal distension			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	3 / 108 (2.78%)	0 / 117 (0.00%)
occurrences (all)	0	3	0
abdominal pain lower			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
abdominal pain upper			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	9 / 122 (7.38%)	13 / 108 (12.04%)	10 / 117 (8.55%)
occurrences (all)	12	14	10
constipation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
diarrhoea			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 122 (1.64%)	4 / 108 (3.70%)	3 / 117 (2.56%)
occurrences (all)	3	4	3
dry mouth			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 122 (1.64%)	3 / 108 (2.78%)	1 / 117 (0.85%)
occurrences (all)	2	3	1
dyspepsia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	3 / 108 (2.78%)	1 / 117 (0.85%)
occurrences (all)	0	4	1
faecal incontinence			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
flatulence			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	1 / 117 (0.85%)
occurrences (all)	0	1	1
food poisoning			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
frequent bowel movements			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1

gastritis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
gastrointestinal sounds abnormal			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
gingival bleeding			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
gingival pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
nausea			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	11 / 122 (9.02%)	18 / 108 (16.67%)	11 / 117 (9.40%)
occurrences (all)	11	20	12
stomatitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
teething			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
tooth crowding			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
tooth impacted			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
toothache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 122 (1.64%)	0 / 108 (0.00%)	3 / 117 (2.56%)
occurrences (all)	2	0	3
vomiting			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	3 / 122 (2.46%)	5 / 108 (4.63%)	2 / 117 (1.71%)
occurrences (all)	3	6	2
Hepatobiliary disorders			
biliary dyskinesia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
hepatic steatosis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
alopecia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
dermatitis contact			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	1	0	2
eczema			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
heat rash			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
hyperhidrosis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	2 / 108 (1.85%)	1 / 117 (0.85%)
occurrences (all)	0	2	1
ingrown hair			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
pain of skin			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
pruritus			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	2 / 108 (1.85%)	0 / 117 (0.00%)
occurrences (all)	1	2	0
rash			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	1 / 108 (0.93%)	1 / 117 (0.85%)
occurrences (all)	1	1	1
rash macular			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0

rash maculo-papular			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
stevens-johnson syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
trichorrhexis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
urticaria			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	1 / 117 (0.85%)
occurrences (all)	0	1	1
Renal and urinary disorders			
enuresis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	3 / 122 (2.46%)	1 / 108 (0.93%)	1 / 117 (0.85%)
occurrences (all)	3	1	1
back pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	2 / 108 (1.85%)	2 / 117 (1.71%)
occurrences (all)	0	2	2
flank pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
joint hyperextension			

alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
muscular weakness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
musculoskeletal stiffness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
myalgia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
neck pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
pain in extremity			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 122 (1.64%)	1 / 108 (0.93%)	3 / 117 (2.56%)
occurrences (all)	2	1	3
temporomandibular joint syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	2	0	0
abscess limb			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
acarodermatitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
acute tonsillitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
bronchitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
cat scratch disease			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
cellulitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
conjunctivitis infective			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0

ear infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
folliculitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
fungal infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
furuncle			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
gastric infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	3 / 108 (2.78%)	0 / 117 (0.00%)
occurrences (all)	0	3	0
gastroenteritis viral			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	2	0
gastrointestinal infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
gastrointestinal viral infection			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
hordeolum			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
infectious mononucleosis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
influenza			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 122 (1.64%)	1 / 108 (0.93%)	1 / 117 (0.85%)
occurrences (all)	2	1	1
kidney infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
laryngitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
nasopharyngitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	3 / 122 (2.46%)	3 / 108 (2.78%)	7 / 117 (5.98%)
occurrences (all)	3	3	8
oral herpes			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0

otitis externa			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	1
otitis media			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
paronychia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	1	0	0
pharyngitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	1	0	1
pharyngitis streptococcal			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 122 (0.82%)	1 / 108 (0.93%)	1 / 117 (0.85%)
occurrences (all)	1	1	1
pharyngotonsillitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
respiratory tract infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
rhinitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
sinusitis			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	3 / 122 (2.46%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	3	1	0
skin infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
staphylococcal skin infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
subcutaneous abscess			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
tonsillitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	6 / 122 (4.92%)	1 / 108 (0.93%)	3 / 117 (2.56%)
occurrences (all)	6	1	3
urinary tract infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
vaginal infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[6]	0 / 69 (0.00%)	1 / 60 (1.67%)	0 / 61 (0.00%)
occurrences (all)	0	1	0
varicella			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0

viral infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	1 / 108 (0.93%)	0 / 117 (0.00%)
occurrences (all)	0	1	0
viral pharyngitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	0	0	2
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	4 / 122 (3.28%)	6 / 108 (5.56%)	6 / 117 (5.13%)
occurrences (all)	4	6	6
dehydration			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
diabetes mellitus			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
hyperlipidaemia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 122 (0.00%)	0 / 108 (0.00%)	0 / 117 (0.00%)
occurrences (all)	0	0	0
increased appetite			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 122 (1.64%)	0 / 108 (0.00%)	1 / 117 (0.85%)
occurrences (all)	2	0	1

Non-serious adverse events	Duloxetine 30 mg_Acute	Placebo/Duloxetine 60-120	Fluoxetine_Extension

		mg_Extension	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	66 / 116 (56.90%)	52 / 82 (63.41%)	45 / 84 (53.57%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
flushing			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
hot flush			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Surgical and medical procedures			
cholecystectomy			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
influenza immunisation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	0	1	1
chest pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0

chills			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
discomfort			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
energy increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
face oedema			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
facial pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
fatigue			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	6 / 116 (5.17%)	6 / 82 (7.32%)	2 / 84 (2.38%)
occurrences (all)	7	7	2
feeling abnormal			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
feeling cold			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
feeling hot			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
feeling jittery			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
feeling of body temperature change			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
hyperthermia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
influenza like illness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
irritability			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 116 (1.72%)	2 / 82 (2.44%)	1 / 84 (1.19%)
occurrences (all)	2	2	1
medical device complication			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	2	0	1
non-cardiac chest pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	1	1	1

pyrexia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	3 / 116 (2.59%)	8 / 82 (9.76%)	1 / 84 (1.19%)
occurrences (all)	4	8	1
sluggishness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
therapeutic response unexpected			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
allergy to animal			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
hypersensitivity			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
seasonal allergy			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	2 / 84 (2.38%)
occurrences (all)	0	0	2
Social circumstances			
menarche			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[1]	0 / 47 (0.00%)	0 / 49 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
victim of sexual abuse			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Reproductive system and breast disorders			

cervical dysplasia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[2]	0 / 47 (0.00%)	0 / 49 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
dysmenorrhoea			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[3]	1 / 47 (2.13%)	2 / 49 (4.08%)	1 / 39 (2.56%)
occurrences (all)	1	2	1
menstruation delayed			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[4]	1 / 47 (2.13%)	0 / 49 (0.00%)	0 / 39 (0.00%)
occurrences (all)	1	0	0
menstruation irregular			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[5]	0 / 47 (0.00%)	0 / 49 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
pruritus genital			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
cough			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	4 / 116 (3.45%)	3 / 82 (3.66%)	5 / 84 (5.95%)
occurrences (all)	4	3	5
epistaxis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
nasal congestion			
alternative dictionary used:			

MedDRA 14.0			
subjects affected / exposed	3 / 116 (2.59%)	3 / 82 (3.66%)	2 / 84 (2.38%)
occurrences (all)	3	3	2
oropharyngeal pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 116 (1.72%)	2 / 82 (2.44%)	0 / 84 (0.00%)
occurrences (all)	2	2	0
rhinitis allergic			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
rhinitis seasonal			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
rhinorrhoea			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	1	1	0
sinus congestion			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
sneezing			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
snoring			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
yawning			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 116 (1.72%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			
abnormal behaviour			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
abnormal dreams			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
aggression			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
agitation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
anger			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
anorexia nervosa			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
anxiety			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	3 / 116 (2.59%)	2 / 82 (2.44%)	0 / 84 (0.00%)
occurrences (all)	3	2	0
bipolar disorder			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
confusional state			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
depression			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	1	1	0
derealisation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
emotional disorder			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
hallucination, auditory			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
hallucination, visual			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
hallucinations, mixed			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0

hypomania			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
impulsive behaviour			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
inappropriate affect			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
initial insomnia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	1	1	1
insomnia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	3 / 116 (2.59%)	2 / 82 (2.44%)	1 / 84 (1.19%)
occurrences (all)	3	2	1
intentional drug misuse			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
intentional self-injury			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 116 (1.72%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	2	1	0
middle insomnia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	2 / 82 (2.44%)	0 / 84 (0.00%)
occurrences (all)	1	2	0
mood swings			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
nervousness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
nightmare			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
pyromania			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
restlessness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
sleep disorder			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
somnambulism			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	2	0	0
suicidal ideation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	2 / 84 (2.38%)
occurrences (all)	0	1	3
tachyphrenia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0

tearfulness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
terminal insomnia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
tic			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
Investigations			
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	0	1	1
blood uric acid increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
heart rate increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
human papilloma virus test positive			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
lymph node palpable			
alternative dictionary used:			

MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
weight decreased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	1	1	0
weight increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
accidental exposure			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
accidental overdose			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	1	1	1
animal bite			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
concussion			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
contusion			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	1	2	0
excoriation			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	2 / 84 (2.38%)
occurrences (all)	0	1	2
facial bones fracture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
fall			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
hand fracture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
head injury			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
inappropriate schedule of drug administration			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
incorrect dose administered			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	4 / 84 (4.76%)
occurrences (all)	1	1	4
intentional overdose			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
joint dislocation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0

joint injury			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
joint sprain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	2 / 84 (2.38%)
occurrences (all)	0	1	2
laceration			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
limb injury			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	2 / 84 (2.38%)
occurrences (all)	0	0	2
muscle rupture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
muscle strain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
periorbital haematoma			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
post concussion syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
procedural dizziness			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
procedural pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
road traffic accident			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
skeletal injury			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
stress fracture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
sunburn			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
thermal burn			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
upper limb fracture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
wrist fracture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	2 / 84 (2.38%)
occurrences (all)	0	0	2

Cardiac disorders			
palpitations			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
aphasia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
cerebral disorder			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
crying			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	0	1	2
delayed sleep phase			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
disturbance in attention			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
dizziness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	10 / 116 (8.62%)	7 / 82 (8.54%)	2 / 84 (2.38%)
occurrences (all)	11	7	2
headache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	20 / 116 (17.24%)	11 / 82 (13.41%)	10 / 84 (11.90%)
occurrences (all)	27	13	14
hyperreflexia			

alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
hypersomnia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 116 (1.72%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	2	1	1
memory impairment			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	0	1	1
migraine			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	1	0	1
paraesthesia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
poor quality sleep			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
post-traumatic headache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
psychomotor hyperactivity			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
sedation			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	2 / 116 (1.72%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	2	1	0
sensory disturbance			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
sinus headache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
somnolence			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	3 / 116 (2.59%)	2 / 82 (2.44%)	0 / 84 (0.00%)
occurrences (all)	3	2	0
syncope			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	1	0	1
tension headache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
tremor			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
iron deficiency anaemia			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
thrombocytosis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	2 / 84 (2.38%)
occurrences (all)	1	0	2
motion sickness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
tinnitus			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
vertigo			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
astigmatism			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
blepharospasm			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
conjunctivitis			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
conjunctivitis allergic			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
eye pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
hypermetropia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
mydriasis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
myopia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
vision blurred			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	4 / 116 (3.45%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	5	0	0
abdominal distension			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
abdominal pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 116 (1.72%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	2	0	1
abdominal pain lower			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
abdominal pain upper			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	10 / 116 (8.62%)	4 / 82 (4.88%)	7 / 84 (8.33%)
occurrences (all)	10	4	7
constipation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
diarrhoea			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	9 / 116 (7.76%)	2 / 82 (2.44%)	5 / 84 (5.95%)
occurrences (all)	9	2	5
dry mouth			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 116 (1.72%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	2	0	0
dyspepsia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
faecal incontinence			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0

flatulence			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
food poisoning			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
frequent bowel movements			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
gastritis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
gastrointestinal sounds abnormal			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
gingival bleeding			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
gingival pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
nausea			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	21 / 116 (18.10%)	8 / 82 (9.76%)	3 / 84 (3.57%)
occurrences (all)	22	10	5
stomatitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
teething			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
tooth crowding			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
tooth impacted			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
toothache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	0	1	1
vomiting			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	7 / 116 (6.03%)	8 / 82 (9.76%)	8 / 84 (9.52%)
occurrences (all)	8	9	8
Hepatobiliary disorders			
biliary dyskinesia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
hepatic steatosis			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	1	1	0
alopecia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
dermatitis contact			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	1	1	1
eczema			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
heat rash			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
hyperhidrosis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
ingrown hair			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
pain of skin			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
pruritus			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	2	0	0
rash			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	1	1	0
rash macular			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 116 (1.72%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	3	0	0
rash maculo-papular			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
stevens-johnson syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
trichorrhexis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
urticaria			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
Renal and urinary disorders			
enuresis			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	2 / 82 (2.44%)	0 / 84 (0.00%)
occurrences (all)	1	2	0
back pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 116 (1.72%)	2 / 82 (2.44%)	1 / 84 (1.19%)
occurrences (all)	2	2	2
flank pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
joint hyperextension			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
muscle spasms			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 116 (1.72%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	2	0	0
muscular weakness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
musculoskeletal stiffness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
myalgia			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
neck pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
pain in extremity			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	2 / 82 (2.44%)	1 / 84 (1.19%)
occurrences (all)	0	2	1
temporomandibular joint syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
abscess limb			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
acarodermatitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
acute tonsillitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
bronchitis			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	2 / 84 (2.38%)
occurrences (all)	0	0	2
cat scratch disease			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
cellulitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
conjunctivitis infective			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
cystitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
ear infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	0	1	2
folliculitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
fungal infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
furuncle			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0

gastric infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
gastroenteritis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
gastroenteritis viral			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	1	1	0
gastrointestinal infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
gastrointestinal viral infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	0	1	1
hordeolum			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	2 / 82 (2.44%)	0 / 84 (0.00%)
occurrences (all)	0	2	0
infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
infectious mononucleosis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
influenza			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	3 / 116 (2.59%)	3 / 82 (3.66%)	2 / 84 (2.38%)
occurrences (all)	3	4	3
kidney infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
laryngitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
nasopharyngitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	4 / 116 (3.45%)	3 / 82 (3.66%)	7 / 84 (8.33%)
occurrences (all)	4	3	8
oral herpes			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
otitis externa			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
otitis media			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	0	1	1
paronychia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 116 (1.72%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	3	0	0
pharyngitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	1	2	1

pharyngitis streptococcal			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 116 (1.72%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	2	1	1
pharyngotonsillitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	1	1	0
respiratory tract infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
rhinitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
sinusitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	2 / 82 (2.44%)	1 / 84 (1.19%)
occurrences (all)	1	2	1
skin infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
staphylococcal skin infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
subcutaneous abscess			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
tonsillitis			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	1 / 116 (0.86%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	1	0	0
upper respiratory tract infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	6 / 116 (5.17%)	2 / 82 (2.44%)	2 / 84 (2.38%)
occurrences (all)	7	3	2
urinary tract infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
vaginal infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[6]	0 / 47 (0.00%)	0 / 49 (0.00%)	0 / 39 (0.00%)
occurrences (all)	0	0	0
varicella			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
viral infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	2
viral pharyngitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	1 / 84 (1.19%)
occurrences (all)	0	0	1
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	10 / 116 (8.62%)	4 / 82 (4.88%)	1 / 84 (1.19%)
occurrences (all)	10	4	1
dehydration			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	0 / 82 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0	0
diabetes mellitus			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
hyperlipidaemia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 116 (0.00%)	1 / 82 (1.22%)	0 / 84 (0.00%)
occurrences (all)	0	1	0
increased appetite			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 116 (0.86%)	1 / 82 (1.22%)	1 / 84 (1.19%)
occurrences (all)	1	1	1

Non-serious adverse events	Duloxetine 60/60-120 mg_Extension	Duloxetine 30/60-120 mg_Extension	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	49 / 73 (67.12%)	46 / 81 (56.79%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
skin papilloma			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
flushing			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
hot flush			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
Surgical and medical procedures			
cholecystectomy			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
influenza immunisation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
chest pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
chills			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
discomfort			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
energy increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
face oedema			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)		
occurrences (all)	1	0		
facial pain				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)		
occurrences (all)	0	1		
fatigue				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	3 / 73 (4.11%)	2 / 81 (2.47%)		
occurrences (all)	3	2		
feeling abnormal				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)		
occurrences (all)	0	0		
feeling cold				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)		
occurrences (all)	0	0		
feeling hot				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)		
occurrences (all)	0	0		
feeling jittery				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)		
occurrences (all)	0	0		
feeling of body temperature change				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)		
occurrences (all)	0	0		
hyperthermia				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)		
occurrences (all)	0	1		

influenza like illness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
irritability			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
medical device complication			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
non-cardiac chest pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	2	
pyrexia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	3 / 73 (4.11%)	3 / 81 (3.70%)	
occurrences (all)	3	4	
sluggishness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
therapeutic response unexpected			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			

allergy to animal			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
hypersensitivity			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 73 (2.74%)	0 / 81 (0.00%)	
occurrences (all)	2	0	
seasonal allergy			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
Social circumstances			
menarche			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[1]	0 / 39 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
victim of sexual abuse			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
cervical dysplasia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[2]	0 / 39 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
dysmenorrhoea			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[3]	1 / 39 (2.56%)	1 / 32 (3.13%)	
occurrences (all)	1	1	
menstruation delayed			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[4]	0 / 39 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
menstruation irregular			

alternative dictionary used: MedDRA 14.0			
subjects affected / exposed[5]	0 / 39 (0.00%)	0 / 32 (0.00%)	
occurrences (all)	0	0	
pruritus genital			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
cough			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 73 (2.74%)	1 / 81 (1.23%)	
occurrences (all)	2	1	
epistaxis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
nasal congestion			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
oropharyngeal pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	3 / 73 (4.11%)	1 / 81 (1.23%)	
occurrences (all)	4	1	
rhinitis allergic			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
rhinitis seasonal			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
rhinorrhoea			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	2	
sinus congestion			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
sneezing			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
snoring			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
upper respiratory tract inflammation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
yawning			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
abnormal behaviour			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
abnormal dreams			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
aggression			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
agitation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
anger			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
anorexia nervosa			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
anxiety			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
bipolar disorder			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
confusional state			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
depression			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	

derealisation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
emotional disorder			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
hallucination, auditory			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
hallucination, visual			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
hallucinations, mixed			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
hypomania			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
impulsive behaviour			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
inappropriate affect			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
initial insomnia			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
insomnia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 73 (2.74%)	4 / 81 (4.94%)	
occurrences (all)	2	5	
intentional drug misuse			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
intentional self-injury			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 73 (2.74%)	2 / 81 (2.47%)	
occurrences (all)	3	2	
middle insomnia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
mood swings			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
nervousness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
nightmare			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 73 (2.74%)	0 / 81 (0.00%)	
occurrences (all)	2	0	
pyromania			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	

restlessness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
sleep disorder			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
somnambulism			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
suicidal ideation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
tachyphrenia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
tearfulness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
terminal insomnia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
tic			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Investigations			

blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 73 (2.74%)	0 / 81 (0.00%)	
occurrences (all)	2	0	
blood uric acid increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
electrocardiogram qt prolonged			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
heart rate increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 73 (2.74%)	0 / 81 (0.00%)	
occurrences (all)	2	0	
human papilloma virus test positive			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
lymph node palpable			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
weight decreased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
weight increased			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 73 (2.74%)	0 / 81 (0.00%)	
occurrences (all)	2	0	
Injury, poisoning and procedural complications			

accidental exposure			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
accidental overdose			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	2 / 81 (2.47%)	
occurrences (all)	0	2	
animal bite			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
concussion			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
contusion			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
excoriation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
facial bones fracture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
fall			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
hand fracture			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
head injury			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
inappropriate schedule of drug administration			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
incorrect dose administered			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	5 / 73 (6.85%)	3 / 81 (3.70%)	
occurrences (all)	5	3	
intentional overdose			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
joint dislocation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
joint injury			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
joint sprain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
laceration			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	

limb injury			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
muscle rupture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
muscle strain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
periorbital haematoma			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
post concussion syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
procedural dizziness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
procedural pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
road traffic accident			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
skeletal injury			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
stress fracture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
sunburn			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
thermal burn			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
upper limb fracture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
wrist fracture			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
palpitations			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
aphasia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
cerebral disorder			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
crying			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
delayed sleep phase			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
disturbance in attention			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
dizziness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 73 (2.74%)	6 / 81 (7.41%)	
occurrences (all)	2	6	
headache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	6 / 73 (8.22%)	4 / 81 (4.94%)	
occurrences (all)	8	4	
hyperreflexia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
hypersomnia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
memory impairment			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	

migraine			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
paraesthesia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
poor quality sleep			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
post-traumatic headache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
psychomotor hyperactivity			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
sedation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 73 (2.74%)	0 / 81 (0.00%)	
occurrences (all)	3	0	
sensory disturbance			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
sinus headache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
somnolence			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
syncope			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
tension headache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
tremor			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
anaemia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
iron deficiency anaemia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
thrombocytosis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
ear pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
motion sickness			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
tinnitus			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
vertigo			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
Eye disorders			
astigmatism			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
blepharospasm			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
conjunctivitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
conjunctivitis allergic			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
eye pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
hypermetropia			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
mydriasis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
myopia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
vision blurred			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
abdominal discomfort			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	3 / 73 (4.11%)	0 / 81 (0.00%)	
occurrences (all)	3	0	
abdominal distension			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
abdominal pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	4 / 73 (5.48%)	1 / 81 (1.23%)	
occurrences (all)	4	1	
abdominal pain lower			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
abdominal pain upper			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	6 / 73 (8.22%)	6 / 81 (7.41%)	
occurrences (all)	8	7	
constipation			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 73 (2.74%)	1 / 81 (1.23%)	
occurrences (all)	2	1	
diarrhoea			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	5 / 81 (6.17%)	
occurrences (all)	1	7	
dry mouth			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
dyspepsia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
faecal incontinence			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
flatulence			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
food poisoning			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
frequent bowel movements			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	

gastritis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
gastrointestinal sounds abnormal			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
gingival bleeding			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
gingival pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
nausea			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	6 / 73 (8.22%)	13 / 81 (16.05%)	
occurrences (all)	7	14	
stomatitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
teething			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
tooth crowding			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
tooth impacted			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
toothache			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
vomiting			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	4 / 73 (5.48%)	10 / 81 (12.35%)	
occurrences (all)	4	13	
Hepatobiliary disorders			
biliary dyskinesia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
hepatic steatosis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
alopecia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
dermatitis contact			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
eczema			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
heat rash			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
hyperhidrosis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
ingrown hair			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
pain of skin			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
pruritus			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
rash			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
rash macular			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	

rash maculo-papular			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
stevens-johnson syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
trichorrhexis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
urticaria			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
enuresis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	2	
back pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 73 (2.74%)	0 / 81 (0.00%)	
occurrences (all)	2	0	
flank pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
joint hyperextension			

alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
muscle spasms			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
muscular weakness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
musculoskeletal stiffness			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
myalgia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
neck pain			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
pain in extremity			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	2 / 73 (2.74%)	1 / 81 (1.23%)	
occurrences (all)	3	1	
temporomandibular joint syndrome			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
abscess			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
abscess limb			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
acarodermatitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
acute tonsillitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
bronchitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
cat scratch disease			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
cellulitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
conjunctivitis infective			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	1	0	
cystitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	

ear infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
folliculitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
fungal infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
furuncle			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)	
occurrences (all)	2	0	
gastric infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
gastroenteritis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	2 / 81 (2.47%)	
occurrences (all)	1	2	
gastroenteritis viral			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
gastrointestinal infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
gastrointestinal viral infection			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	1 / 73 (1.37%)	0 / 81 (0.00%)		
occurrences (all)	1	0		
hordeolum				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)		
occurrences (all)	0	0		
infection				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)		
occurrences (all)	0	1		
infectious mononucleosis				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)		
occurrences (all)	0	0		
influenza				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	3 / 73 (4.11%)	1 / 81 (1.23%)		
occurrences (all)	4	1		
kidney infection				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)		
occurrences (all)	0	0		
laryngitis				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)		
occurrences (all)	0	0		
nasopharyngitis				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	3 / 73 (4.11%)	6 / 81 (7.41%)		
occurrences (all)	3	7		
oral herpes				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)		
occurrences (all)	0	0		

otitis externa			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
otitis media			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
paronychia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
pharyngitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)	
occurrences (all)	1	1	
pharyngitis streptococcal			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	3 / 73 (4.11%)	1 / 81 (1.23%)	
occurrences (all)	3	1	
pharyngotonsillitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
respiratory tract infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
rhinitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
sinusitis			
alternative dictionary used: MedDRA 14.0			

subjects affected / exposed	1 / 73 (1.37%)	1 / 81 (1.23%)		
occurrences (all)	1	1		
skin infection				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)		
occurrences (all)	0	1		
staphylococcal skin infection				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)		
occurrences (all)	0	0		
subcutaneous abscess				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)		
occurrences (all)	0	0		
tonsillitis				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	2 / 81 (2.47%)		
occurrences (all)	0	2		
upper respiratory tract infection				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	5 / 73 (6.85%)	4 / 81 (4.94%)		
occurrences (all)	7	6		
urinary tract infection				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)		
occurrences (all)	0	1		
vaginal infection				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed[6]	0 / 39 (0.00%)	0 / 32 (0.00%)		
occurrences (all)	0	0		
varicella				
alternative dictionary used: MedDRA 14.0				
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)		
occurrences (all)	0	1		

viral infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
viral pharyngitis			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
viral upper respiratory tract infection			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	3 / 81 (3.70%)	
occurrences (all)	0	3	
dehydration			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	1 / 81 (1.23%)	
occurrences (all)	0	1	
diabetes mellitus			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
hyperlipidaemia			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	
increased appetite			
alternative dictionary used: MedDRA 14.0			
subjects affected / exposed	0 / 73 (0.00%)	0 / 81 (0.00%)	
occurrences (all)	0	0	

Notes:

[1] - 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.

[2] - 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.

[3] - 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.

[4] - 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.

[5] - 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.

[6] - 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

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported