Clinical trial results:
A Long-Term, Open-Label, Safety Study of Oral Olanzapine in Adolescents with Bipolar I Disorder (Manic or Mixed Episodes) or Schizophrenia

Summary

EudraCT number	2009-010276-16
Trial protocol	DE
Global end of trial date	07 May 2013

Results information

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

Trial information

Trial identification

Sponsor protocol code	F1D-MC-HGMX

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00982020
WHO universal trial number (UTN)	-
Other trial identifiers	Trial Number: 12117, Trial Alias: F1D-MC-HGMX

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	07 May 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 May 2013
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of this study were to assess in adolescent patients with bipolar I disorder (manic or mixed episode) or schizophrenia: 1) the overall safety of olanzapine for up to approximately 52 weeks of treatment, and 2) whether an Intense behavioral weight intervention program was superior to a Standard behavioral weight intervention program in mitigation of weight gain as assessed by overall mean change from baseline body mass index (BMI).

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 September 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	Germany: 3
Country: Number of subjects enrolled	Poland: 18
Country: Number of subjects enrolled	Russian Federation: 55
Country: Number of subjects enrolled	United States: 107
Country: Number of subjects enrolled	Puerto Rico: 20
Worldwide total number of subjects	203
EEA total number of subjects	21

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)	203
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

No text entered

Pre-assignment

Screening details:

No text entered

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Olanzapine/standard behavioral weight intervention

Arm description:

Olanzapine: 2.5 milligrams (mg) to 20 mg given orally, daily for 52 weeks.
Standard behavioral weight intervention: One time counseling and basic counseling information on healthy eating and exercise habits at randomization visit only

Arm type	Experimental
Investigational medicinal product name	Olanzapine
Investigational medicinal product code	
Other name	Zyprexa, LY170053
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Olanzapine: 2.5 milligrams (mg) to 20 mg given orally, daily for 52 weeks. Standard behavioral weight intervention: One time counseling and basic counseling information on healthy eating and exercise habits at randomization visit only

Arm title	Olanzapine/intense behavioral weight intervention

Arm description:

Olanzapine: 2.5 mg to 20 mg given orally, daily for 52 weeks.
Intense behavioral weight intervention: Counseling provided at randomization and at all subsequent study visits by appropriately trained individual regarding healthy lifestyle habits. Participants also provided with simple tools to help enable healthy eating and exercise habits

Arm type	Experimental
Investigational medicinal product name	Olanzapine
Investigational medicinal product code	
Other name	Zyprexa, LY170053
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Olanzapine: 2.5 mg to 20 mg given orally, daily for 52 weeks. Intense behavioral weight intervention: Counseling provided at randomization and at all subsequent study visits by appropriately trained individual regarding healthy lifestyle habits. Participants also provided with simple tools to help enable healthy eating and exercise habits

Number of subjects in period 1	Olanzapine/standard behavioral weight intervention	Olanzapine/intense behavioral weight intervention
Started	102	101
Received at least 1 dose of study drug	102	101
Completed	45	37
Not completed	57	64
Parent/Caregiver Decision	5	5
Physician decision	2	5
Consent withdrawn by subject	11	14
Clinical Relapse	-	1
Adverse event, non-fatal	19	15
Protocol Violation	-	2
Treatment Non-compliance	3	6
Lost to follow-up	5	11
Entry Criteria Not Met	2	1
Lack of efficacy	10	4

Baseline characteristics

Reporting groups	
Reporting group title	Olanzapine/standard behavioral weight intervention
Reporting group description:	
Olanzapine: 2.5 milligrams (mg) to 20 mg given orally, daily for 52 weeks. Standard behavioral weight intervention: One time counseling and basic counseling information on healthy eating and exercise habits at randomization visit only	
Reporting group title	Olanzapine/intense behavioral weight intervention
Reporting group description:	
Olanzapine: 2.5 mg to 20 mg given orally, daily for 52 weeks. Intense behavioral weight intervention: Counseling provided at randomization and at all subsequent study visits by appropriately trained individual regarding healthy lifestyle habits. Participants also provided with simple tools to help enable healthy eating and exercise habits	

Reporting group values	Olanzapine/standard behavioral weight intervention	Olanzapine/intense behavioral weight intervention	Total
Number of subjects	102	101	203
Age categorical Units: Subjects			
Adolescents (12-17 years)	102	101	203
Age Continuous Units: years			
arithmetic mean	15.86	15.66	
standard deviation	± 1.49	± 1.52	-
Gender, Male/Female Units: participants			
Female	50	47	97
Male	52	54	106
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	15	9	24
Not Hispanic or Latino	87	92	179
Unknown or Not Reported	0	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	1	1
Asian	2	1	3
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	12	14	26
White	84	80	164
More than one race	4	5	9
Unknown or Not Reported	0	0	0
Region of Enrollment Units: Subjects			
Germany	2	1	3
Poland	6	12	18
Russian Federation	28	27	55
United States	53	54	107

Puerto Rico	13	7	20

End points

End points reporting groups

Reporting group title	Olanzapine/standard behavioral weight intervention
Reporting group description:	
Olanzapine: 2.5 milligrams (mg) to 20 mg given orally, daily for 52 weeks. Standard behavioral weight intervention: One time counseling and basic counseling information on healthy eating and exercise habits at randomization visit only	
Reporting group title	Olanzapine/intense behavioral weight intervention
Reporting group description:	
Olanzapine: 2.5 mg to 20 mg given orally, daily for 52 weeks. Intense behavioral weight intervention: Counseling provided at randomization and at all subsequent study visits by appropriately trained individual regarding healthy lifestyle habits. Participants also provided with simple tools to help enable healthy eating and exercise habits	

Primary: Mean Change From Baseline to 52 Weeks in Body Mass Index (BMI) for All Participants

End point title	Mean Change From Baseline to 52 Weeks in Body Mass Index (BMI) for All Participants
End point description:	
End point type	Primary
End point timeframe:	
Baseline, 52 weeks	

End point values	Olanzapine/standard behavioral weight intervention	Olanzapine/intense behavioral weight intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102[1]	101[2]		
Units: kilograms per meter squared (kg/m^2)				
least squares mean (standard error)	3.64 (± 0.39)	2.83 (± 0.4)		

Notes:

[1] - Randomized subjects who received ≥ 1 dose of study drug. Mixed model repeated measures (MMRM)

[2] - Randomized subjects who received ≥ 1 dose of study drug. Mixed model repeated measures (MMRM)

Statistical analyses

Statistical analysis title	Statistical Analysis 1 for End Point 1
Comparison groups	Olanzapine/intense behavioral weight intervention v Olanzapine/standard behavioral weight intervention

Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority[3]
P-value	= 0.15
Method	Mixed models analysis

Notes:

[3] - Mixed model repeated measures analysis terms included baseline BMI, baseline age, gender, intervention group, visit, region, intervention group*visit.

Secondary: Mean change from baseline to Endpoint in Body Mass Index (BMI) for participants with duration of treatment of at least 6 months

End point title	Mean change from baseline to Endpoint in Body Mass Index (BMI) for participants with duration of treatment of at least 6 months

End point description:

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	Olanzapine/standard behavioral weight intervention	Olanzapine/intense behavioral weight intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54[4]	55[5]		
Units: kg/m^2				
least squares mean (standard error)	3.36 (± 0.41)	2.99 (± 0.4)		

Notes:

[4] - Received ≥ 1 dose of study drug with ≥ 6 months data. Last observation carried forward (LOCF)

[5] - Received ≥ 1 dose of study drug with ≥ 6 months data. Last observation carried forward (LOCF)

Statistical analyses

Statistical analysis title	Statistical Analysis 1 for End Point 2
Comparison groups	Olanzapine/intense behavioral weight intervention v Olanzapine/standard behavioral weight intervention
Number of subjects included in analysis	109
Analysis specification	Pre-specified
Analysis type	superiority[6]
P-value	= 0.52
Method	ANCOVA

Notes:

[6] - ANCOVA model terms included: baseline, baseline age, gender, intervention group, and region.

Secondary: Time to event for 7%, 15%, and 25% weight gain for all participants

End point title	Time to event for 7%, 15%, and 25% weight gain for all participants

End point description:

Kaplan-Meier methodology used to estimate time to event. Participants who never reached the target weight gain contributed to the set of patients at risk up to the point at which they discontinued from the

study and were then censored (i.e., removed from the risk set).

65 participants (32%; 34% in Standard Group [SG], 30% in Intense Group [IG]) did not meet 7% weight gain criterion [WGC] by the time they discontinued. 122 participants (60%; 58% in SG, 62% in IG) did not meet 15% WGC by the time they discontinued. 161 participants (79%; 76% in SG, 82% in IG) did not meet 25% WGC by the time they discontinued.

End point type	Secondary
End point timeframe:	
Baseline up to 52 weeks	

End point values	Olanzapine/standard behavioral weight intervention	Olanzapine/intense behavioral weight intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102[7]	101[8]		
Units: days				
median (confidence interval 95%)				
Time to First 7% Weight Gain	57 (44 to 84)	57 (44 to 84)		
Time to First 15% Weight Gain	197 (140 to 359)	198 (141 to 999999)		
Time to First 25% Weight Gain	999999 (999999 to 999999)	99999999 (99999999 to 99999999)		

Notes:

[7] - Insufficient # of events of 25% weight gain in the Standard group to compute.

[8] - Insufficient # of events of 15% and 25% weight gain in the Intense group to compute.

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change from baseline to 52 weeks in Adolescent Structured YoungMania Rating Scale (YMRS) for participants with Bipolar I disorder

End point title	Mean change from baseline to 52 weeks in Adolescent Structured YoungMania Rating Scale (YMRS) for participants with Bipolar I disorder

End point description:

The YMRS is an 11-item scale that measures the severity of manic episodes. Four items are rated on a scale from 0 (symptom not present) to 8 (symptom extremely severe). The remaining items are rated on a scale from 0 (symptom not present) to 4 (symptom extremely severe). The YMRS total score ranges from 0 (symptom not present) to 60 (symptom extremely severe).

End point type	Secondary
End point timeframe:	
Baseline, 52 weeks	

End point values	Olanzapine/standard behavioral weight intervention	Olanzapine/intense behavioral weight intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58[9]	58[10]		
Units: units on a scale				
least squares mean (standard error)	-17.66 (± 1.75)	-12.05 (± 1.92)		

Notes:

[9] - Subjects with bipolar I disorder, who received ≥ 1 dose of study drug. MMRM used

[10] - Subjects with bipolar I disorder, who received ≥ 1 dose of study drug. MMRM used

Statistical analyses

Statistical analysis title	Statistical Analysis 1 for End Point 4
Comparison groups	Olanzapine/standard behavioral weight intervention v Olanzapine/intense behavioral weight intervention
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	superiority[11]
P-value	= 0.008
Method	Mixed models analysis

Notes:

[11] - MMRM analysis terms included baseline, intervention group, visit, region, and intervention group visit.

Secondary: Mean Clinical Global Impression of Improvement (CGI-I) at 52 weeks for All Participants

End point title	Mean Clinical Global Impression of Improvement (CGI-I) at 52 weeks for All Participants

End point description:

The Clinical Global Impression of Improvement (CGI-I) is used by the clinician to record the improvement of illness at the time of assessment. The score ranges from 1 (very much improved) to 7 (very much worse).

End point type	Secondary

End point timeframe:

52 weeks

End point values	Olanzapine/standard behavioral weight intervention	Olanzapine/intense behavioral weight intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102[12]	101[13]		
Units: units on a scale				
least squares mean (standard error)	2.04 (± 0.15)	2.29 (± 0.16)		

Notes:

[12] - Subjects who received ≥ 1 dose of study drug. MMRM used

[13] - Subjects who received ≥ 1 dose of study drug. MMRM used

Statistical analyses

Statistical analysis title	Statistical Analysis 1 for End Point 5
Comparison groups	Olanzapine/intense behavioral weight intervention v Olanzapine/standard behavioral weight intervention
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority[14]
P-value	= 0.266
Method	Mixed models analysis

Notes:

[14] - MMRM analysis terms included intervention group, visit, region, and intervention group visit.

Secondary: Mean change from baseline to 52 weeks in waist circumference for all participants

End point title	Mean change from baseline to 52 weeks in waist circumference for all participants

End point description:

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	Olanzapine/standard behavioral weight intervention	Olanzapine/intense behavioral weight intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102[15]	101[16]		
Units: centimeters (cm)				
least squares mean (standard error)	7.22 (± 1.06)	7.31 (± 1.11)		

Notes:

[15] - Subjects who received ≥ 1 dose of study drug.

[16] - Subjects who received ≥ 1 dose of study drug.

Statistical analyses

Statistical analysis title	Statistical Analysis 1 for End Point 6
Comparison groups	Olanzapine/intense behavioral weight intervention v Olanzapine/standard behavioral weight intervention
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority[17]
P-value	= 0.954
Method	Mixed models analysis

Notes:

[17] - MMRM analysis terms included baseline, baseline age, gender, intervention group, visit, region, and intervention group visit.

Secondary: Mean change from baseline to 52 weeks in Clinical Global Impression - Severity (CGI-S) for All Participants

End point title	Mean change from baseline to 52 weeks in Clinical Global Impression - Severity (CGI-S) for All Participants

End point description:

The CGI-S is used by the clinician to record 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.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	Olanzapine/standard behavioral weight intervention	Olanzapine/intense behavioral weight intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102[18]	101[19]		
Units: units on a scale				
least squares mean (standard error)	-2.06 (± 0.14)	-1.74 (± 0.14)		

Notes:

[18] - Subjects who received ≥ 1 dose of study drug. MMRM used

[19] - Subjects who received ≥ 1 dose of study drug. MMRM used

Statistical analyses

Statistical analysis title	Statistical Analysis 1 for End Point 7
Comparison groups	Olanzapine/intense behavioral weight intervention v Olanzapine/standard behavioral weight intervention
Number of subjects included in analysis	203
Analysis specification	Pre-specified
Analysis type	superiority[20]
P-value	= 0.103
Method	Mixed models analysis

Notes:

[20] - MMRM analysis terms included baseline, intervention group, visit, region, and intervention group*visit.

Secondary: Mean change from baseline to 52 weeks in Anchored Version of the Brief Psychiatric Rating Scale for Children (BPRS-C) for participants with schizophrenia

End point title	Mean change from baseline to 52 weeks in Anchored Version of the Brief Psychiatric Rating Scale for Children (BPRS-C) for participants with schizophrenia

End point description:

The BPRS-C characterizes psychopathology. A total of 21 items are rated on a scale from 0 (not present) to 6 (extremely severe) with a total score ranging from 0 to 126. A decrease in score indicates a reduction in psychopathology.

End point type	Secondary

End point timeframe:

Baseline, 52 weeks

End point values	Olanzapine/standard behavioral weight intervention	Olanzapine/intense behavioral weight intervention		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	44[21]	43[22]		
Units: units on a scale				
least squares mean (standard error)	-28 (± 2.83)	-30.96 (± 2.67)		

Notes:

[21] - Subjects with schizophrenia who received ≥ 1 dose of study drug. MMRM used

[22] - Subjects with schizophrenia who received ≥ 1 dose of study drug. MMRM used

Statistical analyses

Statistical analysis title	Statistical Analysis 1 for End Point 8
Comparison groups	Olanzapine/standard behavioral weight intervention v Olanzapine/intense behavioral weight intervention
Number of subjects included in analysis	87
Analysis specification	Pre-specified
Analysis type	superiority[23]
P-value	= 0.436
Method	Mixed models analysis

Notes:

[23] - MMRM analysis terms included baseline, intervention group, visit, region, and intervention group visit.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Entire Study

Adverse event reporting additional description:

F1D-MC-HGMX

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	16.0

Reporting groups

Reporting group title	Olanzapine/intense behavioral weight intervention

Reporting group description: -

Reporting group title	Olanzapine/standard behavioral weight intervention

Reporting group description: -

Serious adverse events	Olanzapine/intense behavioral weight intervention	Olanzapine/standard behavioral weight intervention	
Total subjects affected by serious adverse events			
subjects affected / exposed	20 / 101 (19.80%)	13 / 102 (12.75%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Injury, poisoning and procedural complications			
acetabulum fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
clavicle fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
craniocerebral injury			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
fall			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
facial bones fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
hip fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
humerus fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
jaw fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
multiple injuries			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

overdose			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
rib fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
traumatic liver injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
traumatic lung injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (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			
neuroleptic malignant syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
irritability			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			

gastroduodenitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
pneumothorax			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
abnormal behaviour			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
aggression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bipolar i disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 101 (3.96%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
bipolar disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
drug abuse			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
hallucination, auditory			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
mental disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
psychotic disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 101 (3.96%)	1 / 102 (0.98%)	
occurrences causally related to treatment / all	2 / 5	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
schizophrenia, paranoid type			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
schizophrenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
suicide attempt			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 101 (0.00%)	2 / 102 (1.96%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
suicidal ideation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	3 / 102 (2.94%)	
occurrences causally related to treatment / all	1 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
gastroenteritis viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Olanzapine/intense behavioral weight intervention	Olanzapine/standard behavioral weight intervention	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	81 / 101 (80.20%)	81 / 102 (79.41%)	
Vascular disorders			
haematoma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
hypotension			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	
occurrences (all)	1	1	
Surgical and medical procedures			
cyst removal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	

wisdom teeth removal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
Pregnancy, puerperium and perinatal conditions			
pregnancy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[1]	1 / 47 (2.13%)	1 / 50 (2.00%)	
occurrences (all)	1	1	
General disorders and administration site conditions			
asthenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	3 / 102 (2.94%)	
occurrences (all)	2	3	
chills			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	2 / 102 (1.96%)	
occurrences (all)	2	2	
chest pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	2 / 102 (1.96%)	
occurrences (all)	0	2	
fatigue			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	6 / 101 (5.94%)	9 / 102 (8.82%)	
occurrences (all)	6	10	
gait disturbance			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
influenza like illness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	

irritability			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 101 (2.97%)	5 / 102 (4.90%)	
occurrences (all)	5	5	
oedema peripheral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	
occurrences (all)	1	2	
pyrexia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 101 (2.97%)	4 / 102 (3.92%)	
occurrences (all)	3	4	
thirst			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
Immune system disorders			
seasonal allergy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	2 / 102 (1.96%)	
occurrences (all)	3	2	
Reproductive system and breast disorders			
amenorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[2]	1 / 47 (2.13%)	2 / 50 (4.00%)	
occurrences (all)	1	2	
breast pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
breast enlargement			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
dysmenorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[3]	1 / 47 (2.13%)	3 / 50 (6.00%)	
occurrences (all)	4	18	
menstruation irregular			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[4]	0 / 47 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
metrorrhagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[5]	0 / 47 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
premenstrual cramps			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[6]	0 / 47 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
asthma			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
cough			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 101 (2.97%)	7 / 102 (6.86%)	
occurrences (all)	5	8	
dyspnoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
epistaxis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	5 / 101 (4.95%)	2 / 102 (1.96%)	
occurrences (all)	6	2	
nasal congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 101 (3.96%)	4 / 102 (3.92%)	
occurrences (all)	4	4	
oropharyngeal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 101 (3.96%)	4 / 102 (3.92%)	
occurrences (all)	5	4	
pharyngeal inflammation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
respiratory disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
respiratory tract congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
rhinitis allergic			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	
occurrences (all)	1	1	
rhinorrhoea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	
occurrences (all)	1	1	
sinus congestion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	2 / 102 (1.96%)	
occurrences (all)	1	2	

throat tightness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
Psychiatric disorders			
abnormal behaviour			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	2 / 102 (1.96%)	
occurrences (all)	0	2	
affect lability			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
affective disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
aggression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	1 / 102 (0.98%)	
occurrences (all)	3	1	
agitation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	2 / 102 (1.96%)	
occurrences (all)	1	2	
anhedonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
anxiety			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 101 (2.97%)	6 / 102 (5.88%)	
occurrences (all)	4	6	
delusion			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	2	
depressed mood			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	
occurrences (all)	1	1	
depression			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	2 / 102 (1.96%)	
occurrences (all)	2	2	
dermatillomania			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
distractibility			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
dysphoria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
emotional distress			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
emotional poverty			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
hallucination, visual			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	

hallucination			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	2 / 102 (1.96%)	
occurrences (all)	0	2	
impulsive behaviour			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
initial insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	2 / 102 (1.96%)	
occurrences (all)	1	2	
insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 101 (4.95%)	5 / 102 (4.90%)	
occurrences (all)	5	6	
intentional self-injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	4 / 102 (3.92%)	
occurrences (all)	1	5	
middle insomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
mood altered			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
mood swings			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
nightmare			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	
occurrences (all)	1	1	
obsessive thoughts			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
panic attack			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	2	0	
psychotic disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
restlessness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 101 (2.97%)	4 / 102 (3.92%)	
occurrences (all)	4	4	
schizophrenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	2 / 102 (1.96%)	
occurrences (all)	2	2	
self injurious behaviour			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
stereotypy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
thought blocking			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	

tachyphrenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
Investigations			
alanine aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 101 (2.97%)	3 / 102 (2.94%)	
occurrences (all)	3	3	
aspartate aminotransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	3 / 102 (2.94%)	
occurrences (all)	1	3	
blood alkaline phosphatase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
blood cholesterol increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	2 / 102 (1.96%)	
occurrences (all)	1	2	
blood creatine phosphokinase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 101 (4.95%)	7 / 102 (6.86%)	
occurrences (all)	6	9	
blood glucose decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
blood glucose increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
blood iron decreased			

alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
blood insulin increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	7 / 101 (6.93%)	10 / 102 (9.80%)	
occurrences (all)	7	11	
blood insulin decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	2 / 102 (1.96%)	
occurrences (all)	2	2	
blood pressure increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
blood prolactin increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	4 / 102 (3.92%)	
occurrences (all)	2	4	
blood triglycerides increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 101 (4.95%)	4 / 102 (3.92%)	
occurrences (all)	5	5	
body mass index increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
body temperature increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	3 / 102 (2.94%)	
occurrences (all)	1	4	
cardiac murmur			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
eosinophil count increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	3 / 102 (2.94%)	
occurrences (all)	1	3	
erythroblast morphology abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
gamma-glutamyltransferase increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
glycosylated haemoglobin increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
hepatic enzyme increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
heart rate increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
hepatitis c antibody positive			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
liver function test abnormal			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	2 / 102 (1.96%)	
occurrences (all)	0	2	

low density lipoprotein increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	3	0	
neutrophil count decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
nitrite urine present			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	2	0	
transaminases increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
waist circumference increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
weight increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	21 / 101 (20.79%)	31 / 102 (30.39%)	
occurrences (all)	21	31	
white blood cell count decreased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
arthropod bite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	
occurrences (all)	1	1	
concussion			
alternative dictionary used:			

MedDRA 16.0				
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)		
occurrences (all)	1	0		
contusion				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	2 / 101 (1.98%)	1 / 102 (0.98%)		
occurrences (all)	2	1		
face injury				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)		
occurrences (all)	1	0		
foot fracture				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)		
occurrences (all)	2	0		
hand fracture				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)		
occurrences (all)	1	0		
intentional overdose				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	2 / 101 (1.98%)	2 / 102 (1.96%)		
occurrences (all)	3	2		
joint injury				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)		
occurrences (all)	0	1		
laceration				
alternative dictionary used: MedDRA 16.0				
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)		
occurrences (all)	0	1		
ligament sprain				
alternative dictionary used: MedDRA 16.0				

subjects affected / exposed	0 / 101 (0.00%)	3 / 102 (2.94%)	
occurrences (all)	0	3	
limb injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 101 (2.97%)	0 / 102 (0.00%)	
occurrences (all)	4	0	
meniscus injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
nerve injury			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
scar			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
sunburn			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
wound			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
wrist fracture			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
sinus tachycardia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
tachycardia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	5 / 102 (4.90%)	
occurrences (all)	1	5	
Nervous system disorders			
akathisia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 101 (3.96%)	5 / 102 (4.90%)	
occurrences (all)	5	6	
bradykinesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
convulsion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	0 / 102 (0.00%)	
occurrences (all)	3	0	
dizziness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	7 / 102 (6.86%)	
occurrences (all)	2	7	
drooling			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	2 / 102 (1.96%)	
occurrences (all)	0	2	
dyskinesia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	2 / 102 (1.96%)	
occurrences (all)	2	2	
disturbance in attention			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 101 (0.99%)	2 / 102 (1.96%)	
occurrences (all)	1	2	
extrapyramidal disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	3 / 102 (2.94%)	
occurrences (all)	2	7	
headache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	20 / 101 (19.80%)	19 / 102 (18.63%)	
occurrences (all)	30	49	
head titubation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
hypersomnia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	4 / 102 (3.92%)	
occurrences (all)	2	5	
lethargy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
migraine			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	
occurrences (all)	1	1	
petit mal epilepsy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
restless legs syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	
occurrences (all)	1	1	

sedation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 101 (2.97%)	8 / 102 (7.84%)	
occurrences (all)	5	8	
somnolence			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	24 / 101 (23.76%)	19 / 102 (18.63%)	
occurrences (all)	28	22	
tremor			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	5 / 101 (4.95%)	3 / 102 (2.94%)	
occurrences (all)	5	3	
Blood and lymphatic system disorders			
agranulocytosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
leukopenia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 101 (3.96%)	2 / 102 (1.96%)	
occurrences (all)	4	2	
lymphadenitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
lymphocytosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
lymphadenopathy			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
neutropenia			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
Ear and labyrinth disorders			
ear disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
ear pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	2 / 102 (1.96%)	
occurrences (all)	1	2	
external ear disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
vertigo			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
Eye disorders			
blepharospasm			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	
occurrences (all)	1	1	
conjunctivitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	2 / 102 (1.96%)	
occurrences (all)	0	2	
eye discharge			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
eye haemorrhage			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
lacrimation increased			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
Gastrointestinal disorders			
abdominal pain upper			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 101 (3.96%)	5 / 102 (4.90%)	
occurrences (all)	4	5	
abdominal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	0 / 102 (0.00%)	
occurrences (all)	2	0	
abdominal discomfort			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	4 / 102 (3.92%)	
occurrences (all)	0	6	
abnormal faeces			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
anal fissure			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
constipation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 101 (3.96%)	1 / 102 (0.98%)	
occurrences (all)	4	1	
diarrhoea			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	3 / 101 (2.97%)	5 / 102 (4.90%)	
occurrences (all)	5	6	
dry mouth			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 101 (3.96%)	6 / 102 (5.88%)	
occurrences (all)	4	6	
dysphagia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
dyspepsia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	3 / 102 (2.94%)	
occurrences (all)	2	3	
gastrooesophageal reflux disease			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	
occurrences (all)	1	1	
glossitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
lip disorder			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
nausea			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 101 (3.96%)	3 / 102 (2.94%)	
occurrences (all)	4	3	
salivary hypersecretion			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	0 / 102 (0.00%)	
occurrences (all)	2	0	

toothache			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	3 / 102 (2.94%)	
occurrences (all)	1	3	
vomiting			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 101 (3.96%)	7 / 102 (6.86%)	
occurrences (all)	7	8	
Skin and subcutaneous tissue disorders			
acne			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	4 / 102 (3.92%)	
occurrences (all)	1	4	
alopecia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
hyperhidrosis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
pruritus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	0 / 102 (0.00%)	
occurrences (all)	2	0	
pruritus generalised			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
rash			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	3 / 102 (2.94%)	
occurrences (all)	1	5	
seborrhoeic dermatitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
skin irritation			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
urticaria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	2	0	
Renal and urinary disorders			
dysuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
enuresis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
pollakiuria			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
arthralgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	0 / 102 (0.00%)	
occurrences (all)	2	0	
back pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	2 / 102 (1.96%)	
occurrences (all)	1	2	
joint stiffness			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	
occurrences (all)	1	1	
medial tibial stress syndrome			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
muscle rigidity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
muscle spasms			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	1 / 102 (0.98%)	
occurrences (all)	3	1	
musculoskeletal pain			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
musculoskeletal stiffness			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 101 (2.97%)	2 / 102 (1.96%)	
occurrences (all)	3	2	
myalgia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	
occurrences (all)	1	1	
pain in extremity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	2 / 102 (1.96%)	
occurrences (all)	0	2	
Infections and infestations			
acute tonsillitis			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
bacterial infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
bronchitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	4 / 101 (3.96%)	3 / 102 (2.94%)	
occurrences (all)	5	3	
chronic tonsillitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
cystitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	0 / 102 (0.00%)	
occurrences (all)	2	0	
ear infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	1 / 102 (0.98%)	
occurrences (all)	2	1	
gastroenteritis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	2	
gastroenteritis rotavirus			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
gastroenteritis viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	3 / 102 (2.94%)	
occurrences (all)	1	3	

herpes zoster			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
influenza			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	3 / 102 (2.94%)	
occurrences (all)	2	3	
localised infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
lower respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
nasopharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	11 / 101 (10.89%)	14 / 102 (13.73%)	
occurrences (all)	11	16	
otitis externa			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
pharyngitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	1 / 102 (0.98%)	
occurrences (all)	1	1	
pharyngitis streptococcal			
alternative dictionary used: MedDRA 16.0			

subjects affected / exposed	1 / 101 (0.99%)	4 / 102 (3.92%)	
occurrences (all)	1	4	
pneumonia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
respiratory tract infection viral			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	1 / 102 (0.98%)	
occurrences (all)	2	1	
sinusitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	3 / 102 (2.94%)	
occurrences (all)	1	4	
tinea pedis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
tonsillitis			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	1	0	
upper respiratory tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	4 / 102 (3.92%)	
occurrences (all)	2	4	
urinary tract infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	3 / 101 (2.97%)	2 / 102 (1.96%)	
occurrences (all)	3	3	
vulvovaginal mycotic infection			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed[7]	0 / 47 (0.00%)	1 / 50 (2.00%)	
occurrences (all)	0	1	

Metabolism and nutrition disorders			
decreased appetite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	2 / 102 (1.96%)	
occurrences (all)	2	2	
hypercholesterolaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	1 / 101 (0.99%)	0 / 102 (0.00%)	
occurrences (all)	2	0	
hyperinsulinaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
hyperlipidaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	2 / 102 (1.96%)	
occurrences (all)	0	2	
hypertriglyceridaemia			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	2 / 102 (1.96%)	
occurrences (all)	2	2	
increased appetite			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	13 / 101 (12.87%)	16 / 102 (15.69%)	
occurrences (all)	14	16	
insulin resistance			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	0 / 101 (0.00%)	1 / 102 (0.98%)	
occurrences (all)	0	1	
obesity			
alternative dictionary used: MedDRA 16.0			
subjects affected / exposed	2 / 101 (1.98%)	2 / 102 (1.96%)	
occurrences (all)	2	2	

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.

[7] - 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