Clinical trial results:
An open label study to evaluate the efficacy, safety and tolerability of RWJ333369 as adjunctive therapy in subjects with partial onset seizure

Due to a system error, the data reported in v1 is not correct and has been removed from public view.

Summary

EudraCT number	2007-001801-99
Trial protocol	HU
Global end of trial date	05 October 2010

Results information

Result version number	v2 (current)
This version publication date	02 June 2016
First version publication date	02 August 2015
Version creation reason	• Correction of full data set Review of data

Trial information

Trial identification

Sponsor protocol code	333369EPY3004

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00991757
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag International N.V.
Sponsor organisation address	Antwerpseweg 15-17, B-2340 Beerse, Belgium,
Public contact	Clinical Registry Group, Clinical Registry Group, +31 71 524 21 66,, ClinicalTrialsEU@its.jnj.com
Scientific contact	Janssen-Cilag International NV, Janssen-Cilag International NV, +31 71 524 21 66,, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 October 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 October 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this open label study is to determine the long-term safety and tolerability of RWJ-333369 as adjunctive treatment of partial onset seizures. Safety evaluation will include worsening of seizures, including rates of status epilepticus.

Protection of trial subjects:

Safety was evaluated by examining the incidence and severity of adverse events; laboratory safety (hematology, serum chemistry, serum lipid profile and urinalysis); Electrocardiogram, vital signs; physical and neurological examination.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 February 2007
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 38
Country: Number of subjects enrolled	Australia: 16
Country: Number of subjects enrolled	Bulgaria: 33
Country: Number of subjects enrolled	Canada: 19
Country: Number of subjects enrolled	China: 110
Country: Number of subjects enrolled	Croatia: 10
Country: Number of subjects enrolled	Czech Republic: 33
Country: Number of subjects enrolled	Finland: 17
Country: Number of subjects enrolled	Germany: 19
Country: Number of subjects enrolled	Hong Kong: 13
Country: Number of subjects enrolled	Hungary: 25
Country: Number of subjects enrolled	India: 137
Country: Number of subjects enrolled	Malaysia: 9
Country: Number of subjects enrolled	Norway: 11
Country: Number of subjects enrolled	Poland: 62
Country: Number of subjects enrolled	Korea, Republic of: 62
Country: Number of subjects enrolled	Russian Federation: 99
Country: Number of subjects enrolled	Sweden: 13
Country: Number of subjects enrolled	Taiwan: 48

Country: Number of subjects enrolled	Thailand: 37
Country: Number of subjects enrolled	Ukraine: 81
Country: Number of subjects enrolled	United States: 118
Worldwide total number of subjects	1010
EEA total number of subjects	223

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)	41
Adults (18-64 years)	952
From 65 to 84 years	17
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was initiated on 12 February 2007 and completed on 5 October 2010 involving subjects from 168 centers in 22 countries.

Pre-assignment

Screening details:

Total 1010 subjects entered the study out of these 445 subjects completed the study while 565 subjects withdraw from the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Carsibamate less than (<) 400 mg

Arm description:

Carsibamate (CRS) tablet modal dose less than 400 mg given orally per day

Arm type	Experimental
Investigational medicinal product name	Carsibamate
Investigational medicinal product code	
Other name	RWJ-333369
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Carsibamate (CRS) tablet modal dose less than 400 mg given orally per day

Arm title	Carisbamate 400-<600mg

Arm description:

Subjects received Carsibamate modal dose from 400 to less than 600 mg given orally per Day.

Arm type	Experimental
Investigational medicinal product name	Carsibamate
Investigational medicinal product code	
Other name	RWJ-333369
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received Carsibamate modal dose from 400 to less than 600 mg given orally per Day.

Arm title	Carisbamate 600-800mg

Arm description:

Subjects received Carsibamate modal dose from 600 to 800 mg given orally per Day.

Arm type	Experimental
Investigational medicinal product name	Carsibamate
Investigational medicinal product code	
Other name	RWJ-333369
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received Carsibamate modal dose from 600 to 800 mg given orally per Day.

Arm title	Carsibamate >800-1000mg

Arm description:

Subjects received Carsibamate modal dose more than 800 to 1000 mg given orally per Day.

Arm type	Experimental
Investigational medicinal product name	Carsibamate
Investigational medicinal product code	
Other name	RWJ-333369
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Subjects received Carsibamate modal dose more than 800 to 1000 mg given orally per Day.

Number of subjects in period 1	Carsibamate less than (<) 400 mg	Carisbamate 400-<600mg	Carisbamate 600-800mg
Started	37	521	450
Completed	10	208	225
Not completed	27	313	225
Adverse event, serious fatal	-	2	5
Consent withdrawn by subject	11	152	89
Adverse event, non-fatal	6	49	16
Other	10	70	86
Pregnancy	-	6	1
Lost to follow-up	-	29	21
Protocol deviation	-	5	7

Number of subjects in period 1	Carsibamate >800-1000mg
Started	2
Completed	2
Not completed	0
Adverse event, serious fatal	-
Consent withdrawn by subject	-
Adverse event, non-fatal	-
Other	-
Pregnancy	-
Lost to follow-up	-
Protocol deviation	-

Baseline characteristics

Reporting groups	
Reporting group title	Carsibamate less than (<) 400 mg
Reporting group description:	
Carsibamate (CRS) tablet modal dose less than 400 mg given orally per day	
Reporting group title	Carisbamate 400-<600mg
Reporting group description:	
Subjects received Carsibamate modal dose from 400 to less than 600 mg given orally per Day.	
Reporting group title	Carisbamate 600-800mg
Reporting group description:	
Subjects received Carsibamate modal dose from 600 to 800 mg given orally per Day.	
Reporting group title	Carsibamate >800-1000mg
Reporting group description:	
Subjects received Carsibamate modal dose more than 800 to 1000 mg given orally per Day.	

Reporting group values	Carsibamate less than (<) 400 mg	Carisbamate 400-<600mg	Carisbamate 600-800mg
Number of subjects	37	521	450
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	3	17	21
Adults (18-64 years)	34	495	421
From 65 to 84 years	0	9	8
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	37.7	35.4	35.5
standard deviation	± 11.84	± 12.74	± 12.9
Title for Gender Units: subjects			
Female	23	276	210
Male	14	245	240

Reporting group values	Carsibamate >800-1000mg	Total	
Number of subjects	2	1010	
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	41	
Adults (18-64 years)	2	952	
From 65 to 84 years	0	17	
85 years and over	0	0	
Title for AgeContinuous Units: years			
arithmetic mean	27		
standard deviation	± 4.24	-	

Title for Gender Units: subjects			
Female	1	510	
Male	1	500	

End points

End points reporting groups

Reporting group title	Carsibamate less than (<) 400 mg
Reporting group description: Carsibamate (CRS) tablet modal dose less than 400 mg given orally per day	
Reporting group title	Carisbamate 400-<600mg
Reporting group description: Subjects received Carsibamate modal dose from 400 to less than 600 mg given orally per Day.	
Reporting group title	Carisbamate 600-800mg
Reporting group description: Subjects received Carsibamate modal dose from 600 to 800 mg given orally per Day.	
Reporting group title	Carsibamate >800-1000mg
Reporting group description: Subjects received Carsibamate modal dose more than 800 to 1000 mg given orally per Day.	
Subject analysis set title	Intent-to-treat (ITT) population
Subject analysis set type	Intention-to-treat
Subject analysis set description: The intent-to treat (ITT) analyses set was defined as subjects who provided seizure diary data for at least 1 visit in the open-label extension.	

Primary: Percentage of Subjects who were Responders

End point title	Percentage of Subjects who were Responders[1]
End point description: Responders were defined as subjects who had at least a 50% reduction from baseline in monthly seizure rate.	
End point type	Primary
End point timeframe: Baseline up to End of Treatment	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics were done, no inferential statistical analyses were performed

End point values	Intent-to-treat (ITT) population			
Subject group type	Subject analysis set			
Number of subjects analysed	1008[2]			
Units: Percentage of Subects				
number (not applicable)	44.5			

Notes:

[2] - ITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Percent Reduction from Baseline to Open-Label Phase in Partial Onset Seizure Frequency

End point title	Percent Reduction from Baseline to Open-Label Phase in Partial Onset Seizure Frequency[3]

End point description:

Change in Partial Onset Seizure Frequency evaluated as the percent reduction from the pretreatment baseline phase in Partial Onset Seizure Frequency compared with the :Open-Label Extension phase

End point type	Primary

End point timeframe:

Baseline up to End of Treatment

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics were done, no inferential statistical analyses were performed

End point values	Intent-to-treat (ITT) population			
Subject group type	Subject analysis set			
Number of subjects analysed	1008[4]			
Units: Percent change				
median (full range (min-max))	43.48 (-398.1 to 100)			

Notes:

[4] - ITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Percent Reduction From Baseline to the Last 6 Months of the Open-Label Phase in Partial Onset Seizure Frequency

End point title	Percent Reduction From Baseline to the Last 6 Months of the Open-Label Phase in Partial Onset Seizure Frequency[5]

End point description:

Change in Partial Onset Seizure Frequency evaluated as the percent reduction from the pretreatment baseline phase in Partial Onset Seizure Frequency compared with the :Open-Label Extension phase

End point type	Primary

End point timeframe:

Baseline upto 6 Months

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics were done, no inferential statistical analyses were performed

End point values	Intent-to-treat (ITT) population			
Subject group type	Subject analysis set			
Number of subjects analysed	1008[6]			
Units: Percent Change				
median (full range (min-max))	49.15 (-748.3 to 100)			

Notes:

[6] - ITT Population

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects who are seizure free from Baseline to Open-Label Phase

End point title	Percentage of Subjects who are seizure free from Baseline to Open-Label Phase[7]

End point description:

Seizure-free days evaluated as the percent change from the pretreatment baseline phase in average monthly seizure-free days per 28 days compared with the Open-Label Phase phase.

End point type	Primary

End point timeframe:

Baseline upto End of treatment

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Descriptive statistics were done, no inferential statistical analyses were performed

End point values	Intent-to-treat (ITT) population			
Subject group type	Subject analysis set			
Number of subjects analysed	962[8]			
Units: Percentage of Subjects				
number (not applicable)	5.8			

Notes:

[8] - ITT Population

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Baseline upto End of treatment	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	12.1

Reporting groups	
Reporting group title	Carsibamate <400 mg
Reporting group description: Carsibamate (CRS) tablet less than 400 mg given orally per day	
Reporting group title	Carsibamate 400-<600mg
Reporting group description: Carsibamate tablet 400 mg to less than 600 mg given orally per day	
Reporting group title	Carisbamate 600-800 mg
Reporting group description: Carsibamate tablet 600 mg to 800 mg given orally per day	
Reporting group title	Carsibamate >800-1000mg
Reporting group description: Carsibamate tablet greater than 800 mg to 1000 mg given orally per day	

Serious adverse events	Carsibamate <400 mg	Carsibamate 400-<600mg	Carisbamate 600-800 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 37 (16.22%)	74 / 521 (14.20%)	70 / 450 (15.56%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Basal Cell Carcinoma			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (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
Breast Cancer			

subjects affected / exposed	0 / 37 (0.00%)	2 / 521 (0.38%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fibroadenoma of Breast			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Lip And/Or Oral Cavity Cancer			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melanocytic Naevus			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Non-Hodgkin's Lymphoma			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oligodendroglioma			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Thyroid Cancer			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Uterine Leiomyoma			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aneurysm Arteriovenous			

subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Surgical and medical procedures			
Arthrodesis			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Pacemaker Insertion			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cataract Operation			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Elective Surgery			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Endocervical Curettage			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Hospitalisation			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hysterectomy			

subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	3 / 450 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical Device Removal			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasal Operation			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Neurosurgery			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cystectomy			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Spinal Fusion Surgery			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgery			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vagal Nerve Stimulator Removal			
subjects affected / exposed	0 / 37 (0.00%)	2 / 521 (0.38%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest Pain			

subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Drowning			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Benign Prostatic Hyperplasia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metrorrhagia			
subjects affected / exposed	0 / 37 (0.00%)	2 / 521 (0.38%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Cyst			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Asphyxia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Aspiration			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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

Respiratory Distress			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Abnormal Behaviour			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute Psychosis			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Aggression			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Agitation			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anxiety			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (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
Conversion Disorder			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			

subjects affected / exposed	0 / 37 (0.00%)	2 / 521 (0.38%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphoria			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Hallucination			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypomania			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major Depression			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic Disorder			
subjects affected / exposed	0 / 37 (0.00%)	2 / 521 (0.38%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide Attempt			
subjects affected / exposed	0 / 37 (0.00%)	3 / 521 (0.58%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Diagnostic Procedure			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Electroencephalogram			

subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Liver Function Test Abnormal			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental Exposure			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Ankle Fracture			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain Contusion			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Haemorrhage Traumatic			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clavicle Fracture			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Concussion			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug Toxicity			

subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural Haematoma			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eyeball Rupture			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Face Injury			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Facial Bones Fracture			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur Fracture			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (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
Head Injury			
subjects affected / exposed	0 / 37 (0.00%)	2 / 521 (0.38%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip Fracture			

subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus Fracture			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	2 / 450 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Lower Limb Fracture			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	2 / 450 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Vertebral Fracture			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Open Wound			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Overdose			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Poisoning			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Road Traffic Accident			

subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Laceration			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skull Fracture			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal Burn			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Traumatic Brain Injury			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	2 / 450 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wrist Fracture			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Congenital, familial and genetic disorders			
Odontogenic Cyst			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Cardiac disorders			
Acute Myocardial Infarction			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Mitral Valve Prolapse			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial Effusion			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Balance Disorder			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Brain Stem Infarction			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral Haematoma			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrosclerosis			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Cerebrovascular Accident			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Coma			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (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
Complex Partial Seizures			

subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	2 / 450 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Convulsion			
subjects affected / exposed	2 / 37 (5.41%)	11 / 521 (2.11%)	5 / 450 (1.11%)
occurrences causally related to treatment / all	0 / 2	1 / 15	1 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Epilepsy			
subjects affected / exposed	1 / 37 (2.70%)	6 / 521 (1.15%)	5 / 450 (1.11%)
occurrences causally related to treatment / all	0 / 1	2 / 8	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Grand Mal Convulsion			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	2 / 450 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage Intracranial			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Headache			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (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
Loss of Consciousness			

subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Memory Impairment			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinsonism			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Partial Seizures			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postictal State			
subjects affected / exposed	0 / 37 (0.00%)	2 / 521 (0.38%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychomotor Hyperactivity			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Speech Disorder			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status Epilepticus			
subjects affected / exposed	0 / 37 (0.00%)	7 / 521 (1.34%)	3 / 450 (0.67%)
occurrences causally related to treatment / all	0 / 0	0 / 7	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Temporal Lobe Epilepsy			

subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Thrombocytopenia			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Vertigo			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Blindness			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
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			
Abdominal Hernia			

subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric Ulcer			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Gastritis			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Gastrointestinal Haemorrhage			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Inguinal Hernia			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis Acute			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	2 / 450 (0.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periproctitis			

subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Salivary Gland Calculus			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small Intestinal Obstruction			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Vomiting			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholecystitis			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gallbladder Non-Functioning			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			

subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash Generalised			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scar			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus Ureteric			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incontinence			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Renal Failure Acute			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Renal Impairment			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Retention			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue			

disorders			
Arthritis			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Back Pain			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Bone Pain			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Spinal Stenosis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin Pain			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral Disc Disorder			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Spinal Stenosis			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Musculoskeletal Chest Pain			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			

subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Neck Pain			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in Extremity			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Osteoarthritis			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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			
Appendicitis			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Bronchopneumonia			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Ear Infection			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Gastroenteritis			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis Viral			

subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Ovarian Infection			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Pelvic Inflammatory Disease			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (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
Plasmodium Falciparum Infection			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	2 / 450 (0.44%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia Primary Atypical			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Pyelonephritis Acute			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	0 / 450 (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
Typhoid Fever			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (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

Serious adverse events	Carsibamate >800-1000mg		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Basal Cell Carcinoma			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast Cancer			

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fibroadenoma of Breast				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lip And/Or Oral Cavity Cancer				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Melanocytic Naevus				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Non-Hodgkin's Lymphoma				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oligodendroglioma				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thyroid Cancer				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Uterine Leiomyoma				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Aneurysm Arteriovenous				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Surgical and medical procedures				
Arthrodesis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac Pacemaker Insertion				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cataract Operation				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Elective Surgery				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocervical Curettage				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hospitalisation				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hysterectomy				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Medical Device Removal				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nasal Operation				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neurosurgery				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian Cystectomy				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal Fusion Surgery				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Surgery				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vagal Nerve Stimulator Removal				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Chest Pain				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drowning				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Reproductive system and breast disorders				
Benign Prostatic Hyperplasia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metrorrhagia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian Cyst				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Asphyxia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia Aspiration				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Respiratory Distress				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Abnormal Behaviour				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute Psychosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aggression				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Agitation				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anxiety				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Conversion Disorder				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Delirium				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Depression				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dysphoria				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hallucination				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypomania				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Major Depression				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychotic Disorder				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Suicide Attempt				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Diagnostic Procedure				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Electroencephalogram				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver Function Test Abnormal				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Accidental Exposure				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ankle Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain Contusion				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral Haemorrhage Traumatic				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clavicle Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Concussion				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Drug Toxicity				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Extradural Haematoma				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eyeball Rupture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Face Injury				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Facial Bones Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femur Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Head Injury				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hip Fracture				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Humerus Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lower Limb Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar Vertebral Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Open Wound				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Overdose				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Poisoning				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Road Traffic Accident				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin Laceration				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skull Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thermal Burn				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Traumatic Brain Injury				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wrist Fracture				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Congenital, familial and genetic disorders				
Odontogenic Cyst				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute Myocardial Infarction				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Mitral Valve Prolapse				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial Effusion				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Balance Disorder				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brain Stem Infarction				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebral Haematoma				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrosclerosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular Accident				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Coma				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Complex Partial Seizures				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Convulsion				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Epilepsy				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Grand Mal Convulsion				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemorrhage Intracranial				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Loss of Consciousness				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Memory Impairment				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parkinsonism				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Partial Seizures				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postictal State				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychomotor Hyperactivity				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Speech Disorder				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Status Epilepticus				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Temporal Lobe Epilepsy				

subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Transient Ischaemic Attack			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Blindness			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal Hernia			

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric Ulcer				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastritis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal Haemorrhage				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal Hernia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Melaena				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis Acute				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Periproctitis				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Salivary Gland Calculus				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small Intestinal Obstruction				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Cholecystitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cholelithiasis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gallbladder Non-Functioning				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Jaundice				

subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Rash Generalised			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Scar			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Calculus Ureteric			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Incontinence			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal Failure Acute			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal Impairment			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary Retention			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue			

disorders				
Arthritis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Back Pain				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bone Pain				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cervical Spinal Stenosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Groin Pain				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intervertebral Disc Disorder				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar Spinal Stenosis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal Chest Pain				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myalgia				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neck Pain				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in Extremity				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal Osteoarthritis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Appendicitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bronchopneumonia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ear Infection				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastroenteritis Viral				

subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ovarian Infection				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pelvic Inflammatory Disease				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Plasmodium Falciparum Infection				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia Primary Atypical				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis Acute				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				

subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Typhoid Fever			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary Tract Infection			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Carsibamate <400 mg	Carsibamate 400-<600mg	Carisbamate 600-800 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	32 / 37 (86.49%)	290 / 521 (55.66%)	314 / 450 (69.78%)
Vascular disorders			
Hot Flush			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences (all)	1	3	0
Hypertension			
subjects affected / exposed	1 / 37 (2.70%)	8 / 521 (1.54%)	15 / 450 (3.33%)
occurrences (all)	15	26	34
Hypotension			
subjects affected / exposed	1 / 37 (2.70%)	3 / 521 (0.58%)	1 / 450 (0.22%)
occurrences (all)	3	10	1
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	2 / 37 (5.41%)	16 / 521 (3.07%)	19 / 450 (4.22%)
occurrences (all)	4	25	21
Chest Discomfort			
subjects affected / exposed	1 / 37 (2.70%)	5 / 521 (0.96%)	5 / 450 (1.11%)
occurrences (all)	1	8	5
Chest Pain			
subjects affected / exposed	2 / 37 (5.41%)	5 / 521 (0.96%)	7 / 450 (1.56%)
occurrences (all)	32	5	11
Chills			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences (all)	1	1	1
Fatigue			
subjects affected / exposed	8 / 37 (21.62%)	25 / 521 (4.80%)	31 / 450 (6.89%)
occurrences (all)	10	30	45
Feeling Cold			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Gait Disturbance			
subjects affected / exposed	0 / 37 (0.00%)	3 / 521 (0.58%)	5 / 450 (1.11%)
occurrences (all)	0	3	7
Irritability			
subjects affected / exposed	3 / 37 (8.11%)	16 / 521 (3.07%)	10 / 450 (2.22%)
occurrences (all)	4	31	11
Oedema Peripheral			
subjects affected / exposed	1 / 37 (2.70%)	3 / 521 (0.58%)	4 / 450 (0.89%)
occurrences (all)	1	3	5
Pyrexia			
subjects affected / exposed	4 / 37 (10.81%)	17 / 521 (3.26%)	26 / 450 (5.78%)
occurrences (all)	4	24	29
Sense of Oppression			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Seasonal Allergy			

subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	4 / 450 (0.89%)
occurrences (all)	1	1	6
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	1 / 37 (2.70%)	3 / 521 (0.58%)	2 / 450 (0.44%)
occurrences (all)	1	29	7
Hypomenorrhoea			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchitis Chronic			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Cough			
subjects affected / exposed	0 / 37 (0.00%)	7 / 521 (1.34%)	10 / 450 (2.22%)
occurrences (all)	0	7	10
Dyspnoea			
subjects affected / exposed	1 / 37 (2.70%)	2 / 521 (0.38%)	4 / 450 (0.89%)
occurrences (all)	1	2	4
Epistaxis			
subjects affected / exposed	1 / 37 (2.70%)	2 / 521 (0.38%)	4 / 450 (0.89%)
occurrences (all)	1	2	7
Hyperventilation			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences (all)	1	0	2
Nasal Congestion			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	2 / 450 (0.44%)
occurrences (all)	1	1	2
Rhinitis Allergic			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal Pain			
subjects affected / exposed	2 / 37 (5.41%)	6 / 521 (1.15%)	8 / 450 (1.78%)
occurrences (all)	3	6	9
Rhinorrhoea			

subjects affected / exposed	1 / 37 (2.70%)	3 / 521 (0.58%)	2 / 450 (0.44%)
occurrences (all)	1	3	2
Sinus Congestion			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	2 / 450 (0.44%)
occurrences (all)	1	0	2
Psychiatric disorders			
Aggression			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	3 / 450 (0.67%)
occurrences (all)	1	1	3
Anxiety			
subjects affected / exposed	3 / 37 (8.11%)	9 / 521 (1.73%)	15 / 450 (3.33%)
occurrences (all)	4	9	20
Depression			
subjects affected / exposed	1 / 37 (2.70%)	10 / 521 (1.92%)	16 / 450 (3.56%)
occurrences (all)	1	11	19
Disturbance in Social Behaviour			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Dysphoria			
subjects affected / exposed	0 / 37 (0.00%)	7 / 521 (1.34%)	0 / 450 (0.00%)
occurrences (all)	0	7	0
Insomnia			
subjects affected / exposed	4 / 37 (10.81%)	26 / 521 (4.99%)	26 / 450 (5.78%)
occurrences (all)	6	42	29
Libido Decreased			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences (all)	1	1	0
Nervousness			
subjects affected / exposed	0 / 37 (0.00%)	7 / 521 (1.34%)	1 / 450 (0.22%)
occurrences (all)	0	8	1
Stress			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Suicidal Ideation			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	5 / 450 (1.11%)
occurrences (all)	1	1	5

Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 37 (0.00%)	8 / 521 (1.54%)	7 / 450 (1.56%)
occurrences (all)	0	9	7
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 37 (0.00%)	4 / 521 (0.77%)	6 / 450 (1.33%)
occurrences (all)	0	5	6
Blood Pressure Increased			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	4 / 450 (0.89%)
occurrences (all)	1	1	9
Weight Decreased			
subjects affected / exposed	0 / 37 (0.00%)	7 / 521 (1.34%)	12 / 450 (2.67%)
occurrences (all)	0	11	12
Weight Increased			
subjects affected / exposed	0 / 37 (0.00%)	2 / 521 (0.38%)	5 / 450 (1.11%)
occurrences (all)	0	2	5
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	2 / 37 (5.41%)	10 / 521 (1.92%)	13 / 450 (2.89%)
occurrences (all)	3	11	19
Excoriation			
subjects affected / exposed	1 / 37 (2.70%)	5 / 521 (0.96%)	8 / 450 (1.78%)
occurrences (all)	1	5	9
Fall			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	7 / 450 (1.56%)
occurrences (all)	0	1	10
Head Injury			
subjects affected / exposed	0 / 37 (0.00%)	6 / 521 (1.15%)	1 / 450 (0.22%)
occurrences (all)	0	7	6
Joint Injury			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	4 / 450 (0.89%)
occurrences (all)	1	1	4
Laceration			
subjects affected / exposed	0 / 37 (0.00%)	2 / 521 (0.38%)	12 / 450 (2.67%)
occurrences (all)	0	2	16
Ligament Sprain			

subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Skin Laceration			
subjects affected / exposed	1 / 37 (2.70%)	4 / 521 (0.77%)	16 / 450 (3.56%)
occurrences (all)	1	8	19
Thermal Burn			
subjects affected / exposed	0 / 37 (0.00%)	5 / 521 (0.96%)	6 / 450 (1.33%)
occurrences (all)	0	5	6
Wound			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	2 / 450 (0.44%)
occurrences (all)	1	1	2
Cardiac disorders			
Cardiac Discomfort			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Palpitations			
subjects affected / exposed	0 / 37 (0.00%)	6 / 521 (1.15%)	3 / 450 (0.67%)
occurrences (all)	0	6	4
Nervous system disorders			
Ageusia			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Agnosia			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Amnesia			
subjects affected / exposed	1 / 37 (2.70%)	5 / 521 (0.96%)	3 / 450 (0.67%)
occurrences (all)	1	5	8
Ataxia			
subjects affected / exposed	0 / 37 (0.00%)	2 / 521 (0.38%)	9 / 450 (2.00%)
occurrences (all)	0	2	12
Balance Disorder			
subjects affected / exposed	0 / 37 (0.00%)	6 / 521 (1.15%)	9 / 450 (2.00%)
occurrences (all)	0	7	12
Convulsion			

subjects affected / exposed	5 / 37 (13.51%)	19 / 521 (3.65%)	33 / 450 (7.33%)
occurrences (all)	5	24	44
Dizziness			
subjects affected / exposed	11 / 37 (29.73%)	57 / 521 (10.94%)	87 / 450 (19.33%)
occurrences (all)	26	118	312
Disturbance in Attention			
subjects affected / exposed	0 / 37 (0.00%)	10 / 521 (1.92%)	7 / 450 (1.56%)
occurrences (all)	0	11	8
Facial Palsy			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Head Discomfort			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	2 / 450 (0.44%)
occurrences (all)	1	0	2
Headache			
subjects affected / exposed	10 / 37 (27.03%)	91 / 521 (17.47%)	83 / 450 (18.44%)
occurrences (all)	48	646	514
Hypoaesthesia			
subjects affected / exposed	0 / 37 (0.00%)	5 / 521 (0.96%)	5 / 450 (1.11%)
occurrences (all)	0	7	6
Hypotonia			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Lethargy			
subjects affected / exposed	1 / 37 (2.70%)	3 / 521 (0.58%)	3 / 450 (0.67%)
occurrences (all)	1	4	3
Memory Impairment			
subjects affected / exposed	0 / 37 (0.00%)	8 / 521 (1.54%)	11 / 450 (2.44%)
occurrences (all)	0	8	13
Migraine			
subjects affected / exposed	1 / 37 (2.70%)	4 / 521 (0.77%)	9 / 450 (2.00%)
occurrences (all)	1	5	19
Nystagmus			
subjects affected / exposed	0 / 37 (0.00%)	4 / 521 (0.77%)	5 / 450 (1.11%)
occurrences (all)	0	4	9
Paraesthesia			

subjects affected / exposed	1 / 37 (2.70%)	7 / 521 (1.34%)	7 / 450 (1.56%)
occurrences (all)	1	10	8
Poor Quality Sleep			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences (all)	1	0	1
Postictal State			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences (all)	1	0	1
Sedation			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Simple Partial Seizures			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	2	0	0
Somnolence			
subjects affected / exposed	0 / 37 (0.00%)	24 / 521 (4.61%)	37 / 450 (8.22%)
occurrences (all)	0	26	47
Tension Headache			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	2 / 450 (0.44%)
occurrences (all)	1	1	3
Tremor			
subjects affected / exposed	0 / 37 (0.00%)	8 / 521 (1.54%)	12 / 450 (2.67%)
occurrences (all)	0	8	26
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 37 (2.70%)	7 / 521 (1.34%)	3 / 450 (0.67%)
occurrences (all)	1	10	3
Ear and labyrinth disorders			
Ear Pain			
subjects affected / exposed	1 / 37 (2.70%)	2 / 521 (0.38%)	3 / 450 (0.67%)
occurrences (all)	2	2	4
Vertigo			
subjects affected / exposed	0 / 37 (0.00%)	10 / 521 (1.92%)	11 / 450 (2.44%)
occurrences (all)	0	17	30
Eye disorders			

Cataract			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	3 / 450 (0.67%)
occurrences (all)	2	1	3
Diplopia			
subjects affected / exposed	0 / 37 (0.00%)	5 / 521 (0.96%)	16 / 450 (3.56%)
occurrences (all)	0	6	46
Eye Movement Disorder			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Lacrimation Increased			
subjects affected / exposed	1 / 37 (2.70%)	2 / 521 (0.38%)	0 / 450 (0.00%)
occurrences (all)	1	2	0
Vision Blurred			
subjects affected / exposed	3 / 37 (8.11%)	9 / 521 (1.73%)	20 / 450 (4.44%)
occurrences (all)	9	11	33
Visual Acuity Reduced			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	5 / 450 (1.11%)
occurrences (all)	0	1	5
Visual Impairment			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences (all)	1	1	1
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	2 / 37 (5.41%)	6 / 521 (1.15%)	9 / 450 (2.00%)
occurrences (all)	5	59	10
Abdominal Pain Lower			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences (all)	1	1	1
Abdominal Pain Upper			
subjects affected / exposed	4 / 37 (10.81%)	11 / 521 (2.11%)	13 / 450 (2.89%)
occurrences (all)	4	22	17
Aphthous Stomatitis			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	2 / 450 (0.44%)
occurrences (all)	1	1	7
Constipation			

subjects affected / exposed	3 / 37 (8.11%)	14 / 521 (2.69%)	12 / 450 (2.67%)
occurrences (all)	3	15	15
Diarrhoea			
subjects affected / exposed	3 / 37 (8.11%)	20 / 521 (3.84%)	23 / 450 (5.11%)
occurrences (all)	6	26	32
Duodenitis			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	1 / 37 (2.70%)	9 / 521 (1.73%)	20 / 450 (4.44%)
occurrences (all)	1	14	35
Gastric Ulcer			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences (all)	1	1	0
Gastritis			
subjects affected / exposed	1 / 37 (2.70%)	9 / 521 (1.73%)	4 / 450 (0.89%)
occurrences (all)	1	10	4
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	6 / 450 (1.33%)
occurrences (all)	0	1	7
Nausea			
subjects affected / exposed	5 / 37 (13.51%)	26 / 521 (4.99%)	27 / 450 (6.00%)
occurrences (all)	6	34	40
Periodontitis			
subjects affected / exposed	1 / 37 (2.70%)	2 / 521 (0.38%)	2 / 450 (0.44%)
occurrences (all)	1	2	2
Rectal Haemorrhage			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Toothache			
subjects affected / exposed	1 / 37 (2.70%)	5 / 521 (0.96%)	5 / 450 (1.11%)
occurrences (all)	1	8	5
Vomiting			
subjects affected / exposed	4 / 37 (10.81%)	26 / 521 (4.99%)	21 / 450 (4.67%)
occurrences (all)	10	29	34
Skin and subcutaneous tissue disorders			

Alopecia			
subjects affected / exposed	0 / 37 (0.00%)	8 / 521 (1.54%)	6 / 450 (1.33%)
occurrences (all)	0	8	7
Decubitus Ulcer			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Dermal Cyst			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	0 / 37 (0.00%)	7 / 521 (1.34%)	5 / 450 (1.11%)
occurrences (all)	0	7	5
Hypoaesthesia Facial			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 37 (0.00%)	9 / 521 (1.73%)	14 / 450 (3.11%)
occurrences (all)	0	11	17
Pruritus			
subjects affected / exposed	2 / 37 (5.41%)	3 / 521 (0.58%)	8 / 450 (1.78%)
occurrences (all)	3	3	8
Urticaria			
subjects affected / exposed	0 / 37 (0.00%)	3 / 521 (0.58%)	5 / 450 (1.11%)
occurrences (all)	0	3	5
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	5 / 450 (1.11%)
occurrences (all)	0	1	5
Polyuria			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	0 / 450 (0.00%)
occurrences (all)	1	1	0
Urinary Tract Pain			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	1 / 37 (2.70%)	6 / 521 (1.15%)	15 / 450 (3.33%)
occurrences (all)	3	10	17
Back Pain			
subjects affected / exposed	2 / 37 (5.41%)	17 / 521 (3.26%)	22 / 450 (4.89%)
occurrences (all)	2	21	38
Bone Pain			
subjects affected / exposed	1 / 37 (2.70%)	2 / 521 (0.38%)	2 / 450 (0.44%)
occurrences (all)	1	35	2
Flank Pain			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences (all)	1	0	1
Muscle Spasms			
subjects affected / exposed	1 / 37 (2.70%)	2 / 521 (0.38%)	0 / 450 (0.00%)
occurrences (all)	1	2	0
Musculoskeletal Pain			
subjects affected / exposed	3 / 37 (8.11%)	4 / 521 (0.77%)	8 / 450 (1.78%)
occurrences (all)	3	7	8
Musculoskeletal Stiffness			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 37 (0.00%)	10 / 521 (1.92%)	11 / 450 (2.44%)
occurrences (all)	0	15	14
Neck Pain			
subjects affected / exposed	2 / 37 (5.41%)	2 / 521 (0.38%)	1 / 450 (0.22%)
occurrences (all)	2	2	1
Pain in Extremity			
subjects affected / exposed	2 / 37 (5.41%)	6 / 521 (1.15%)	13 / 450 (2.89%)
occurrences (all)	2	6	13
Tenosynovitis			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Bronchitis			

subjects affected / exposed	2 / 37 (5.41%)	2 / 521 (0.38%)	9 / 450 (2.00%)
occurrences (all)	3	4	12
Candidiasis			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	2	0	0
Ear Infection			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	7 / 450 (1.56%)
occurrences (all)	0	1	8
Gastroenteritis			
subjects affected / exposed	0 / 37 (0.00%)	2 / 521 (0.38%)	6 / 450 (1.33%)
occurrences (all)	0	2	8
Gastroenteritis Viral			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	4 / 450 (0.89%)
occurrences (all)	2	2	4
Influenza			
subjects affected / exposed	4 / 37 (10.81%)	9 / 521 (1.73%)	19 / 450 (4.22%)
occurrences (all)	4	10	26
Laryngitis			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences (all)	1	1	1
Nasopharyngitis			
subjects affected / exposed	7 / 37 (18.92%)	37 / 521 (7.10%)	46 / 450 (10.22%)
occurrences (all)	10	60	84
Pharyngitis			
subjects affected / exposed	0 / 37 (0.00%)	9 / 521 (1.73%)	12 / 450 (2.67%)
occurrences (all)	0	9	14
Sinusitis			
subjects affected / exposed	1 / 37 (2.70%)	3 / 521 (0.58%)	7 / 450 (1.56%)
occurrences (all)	3	3	9
Tonsillitis			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	1 / 450 (0.22%)
occurrences (all)	1	0	1
Upper Respiratory Tract Infection			
subjects affected / exposed	1 / 37 (2.70%)	21 / 521 (4.03%)	60 / 450 (13.33%)
occurrences (all)	1	30	102
Urinary Tract Infection			

subjects affected / exposed	1 / 37 (2.70%)	10 / 521 (1.92%)	19 / 450 (4.22%)
occurrences (all)	2	13	21
Viral Infection			
subjects affected / exposed	0 / 37 (0.00%)	0 / 521 (0.00%)	8 / 450 (1.78%)
occurrences (all)	0	0	10
Metabolism and nutrition disorders			
Appetite Disorder			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	1 / 450 (0.22%)
occurrences (all)	1	1	1
Decreased Appetite			
subjects affected / exposed	3 / 37 (8.11%)	20 / 521 (3.84%)	14 / 450 (3.11%)
occurrences (all)	4	25	15
Hypercholesterolaemia			
subjects affected / exposed	0 / 37 (0.00%)	1 / 521 (0.19%)	5 / 450 (1.11%)
occurrences (all)	0	1	6
Hyponatraemia			
subjects affected / exposed	1 / 37 (2.70%)	1 / 521 (0.19%)	2 / 450 (0.44%)
occurrences (all)	1	1	2
Polydipsia			
subjects affected / exposed	1 / 37 (2.70%)	0 / 521 (0.00%)	0 / 450 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Carsibamate >800-1000mg		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)		
Vascular disorders			
Hot Flush			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Chest Discomfort			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Chest Pain			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Chills			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Feeling Cold			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Gait Disturbance			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Irritability			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Oedema Peripheral			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Sense of Oppression			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Immune system disorders			
Seasonal Allergy			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Hypomenorrhoea			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Bronchitis Chronic			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Cough			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Hyperventilation			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Nasal Congestion			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Rhinitis Allergic			
subjects affected / exposed	1 / 2 (50.00%)		
occurrences (all)	1		
Oropharyngeal Pain			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Sinus Congestion			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Aggression			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Depression			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Disturbance in Social Behaviour			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Dysphoria			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Libido Decreased			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Nervousness			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Stress			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Suicidal Ideation			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		

Investigations			
Alanine Aminotransferase Increased			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Aspartate Aminotransferase Increased			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Blood Pressure Increased			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Weight Decreased			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Weight Increased			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Excoriation			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Head Injury			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Joint Injury			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Laceration			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Ligament Sprain			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Skin Laceration			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Thermal Burn			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Wound			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Cardiac Discomfort			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Palpitations			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Ageusia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Agnosia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Amnesia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Ataxia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Balance Disorder			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Convulsion			

subjects affected / exposed	1 / 2 (50.00%)			
occurrences (all)	1			
Dizziness				
subjects affected / exposed	2 / 2 (100.00%)			
occurrences (all)	2			
Disturbance in Attention				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Facial Palsy				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Head Discomfort				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Headache				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Hypoaesthesia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Hypotonia				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Lethargy				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Memory Impairment				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Migraine				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Nystagmus				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Paraesthesia				

subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Poor Quality Sleep			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Postictal State			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Sedation			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Simple Partial Seizures			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Tension Headache			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear Pain			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Eye disorders			

Cataract			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Diplopia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Eye Movement Disorder			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Lacrimation Increased			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Vision Blurred			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Visual Acuity Reduced			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Visual Impairment			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal Pain			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Abdominal Pain Lower			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Abdominal Pain Upper			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Aphthous Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Constipation			

subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Duodenitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	1 / 2 (50.00%)		
occurrences (all)	1		
Gastric Ulcer			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	1 / 2 (50.00%)		
occurrences (all)	1		
Gastrooesophageal Reflux Disease			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Periodontitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Rectal Haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			

Alopecia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Decubitus Ulcer subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Dermal Cyst subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Eczema subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Hypoaesthesia Facial subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Rash subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Pruritus subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Urticaria subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Renal and urinary disorders			
Dysuria subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Polyuria subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Urinary Tract Pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0		
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Back Pain			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Bone Pain			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Flank Pain			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Muscle Spasms			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Musculoskeletal Pain			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Musculoskeletal Stiffness			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Neck Pain			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Pain in Extremity			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Tenosynovitis			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Bronchitis			

subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Candidiasis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Ear Infection				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Gastroenteritis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Gastroenteritis Viral				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Influenza				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Laryngitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Nasopharyngitis				
subjects affected / exposed	1 / 2 (50.00%)			
occurrences (all)	5			
Pharyngitis				
subjects affected / exposed	1 / 2 (50.00%)			
occurrences (all)	2			
Sinusitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Tonsillitis				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Upper Respiratory Tract Infection				
subjects affected / exposed	0 / 2 (0.00%)			
occurrences (all)	0			
Urinary Tract Infection				

subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Viral Infection			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Appetite Disorder			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Decreased Appetite			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Hypercholesterolaemia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		
Polydipsia			
subjects affected / exposed	0 / 2 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
02 February 2007	Decreased the required stable duration of concomitant antiepileptic drug (AED) dosage to be for at least 1 month prior to enrollment; increased monitoring frequency for the occurrence of withdrawal symptoms, and updated the time and events schedule to reflect changes in study procedures
04 September 2007	It clarified the endpoint for registration in the United States and the Rest of the World, evaluation and measurement of QTc interval using Fridericia's correction (QTcF), and added additional cardiac-related outcomes
02 November 2007	It included appropriate corrections to maintain consistency between the synopsis and report body and updates according to amendment INT-2
08 September 2008	It included increase in the maximum allowed dose in the open-label extension phase from 800 mg per day to 1200 mg per day, replacement of RWJ-333369 by carisbamate to promote name recognition in sections on open-label extension, and added rationales for permitting slow study drug tapering schedule and dosage strengths of the tablets available in the open-label extension phase
14 October 2009	It included additional withdrawal criteria regarding potential symptoms of Drug Rash with Eosinophilia and Systemic Signs

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported