Clinical trial results:
A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Carisbamate as Adjunctive Therapy in Subjects With Partial Onset Seizures Followed by an Open Label Extension Portion of the Study

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

Summary

EudraCT number	2008-007688-17
Trial protocol	LT
Global end of trial date	31 August 2010

Results information

Result version number	v2 (current)
This version publication date	02 June 2016
First version publication date	30 July 2015
Version creation reason	• Correction of full data set Review of data

Trial information

Trial identification

Sponsor protocol code	CARISEPY3014

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00744731
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen Cilag International, NV
Sponsor organisation address	Archimedsweg 29-2333CM, Leiden, Netherlands, B235-0
Public contact	Clinical Registry Group, Janssen Cilag International, NV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen Cilag International, NV, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-000360-PIP01-08
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	31 August 2010
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	31 August 2010
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The Primary objective of this study was to provide long-term safety and tolerability information on carisbamate as add-on therapy for the treatment of partial onset seizures in Participants with epilepsy. CARISEPY3014/CARISEPY3013 is the open-label extension study that follows the double-blind study .

Protection of trial subjects:

The safety assessments included the incidence and severity of Adverse events (AEs),laboratory safety (hematology, serum chemistry and urinalysis), 12-lead Electrocardiogram (ECG),vital signs, physical and neurological examinations, and seizure rates, Quality of Life in Epilepsy-31 Problems (QOLIE-31-P) and Medical Resource Utilization (MRU) responses were assessed throughout the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 April 2009
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	1 Years
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 19
Country: Number of subjects enrolled	Belgium: 13
Country: Number of subjects enrolled	Croatia: 10
Country: Number of subjects enrolled	Finland: 6
Country: Number of subjects enrolled	Germany: 26
Country: Number of subjects enrolled	Hong Kong: 8
Country: Number of subjects enrolled	India: 36
Country: Number of subjects enrolled	Italy: 12
Country: Number of subjects enrolled	Lithuania: 10
Country: Number of subjects enrolled	Mexico: 12
Country: Number of subjects enrolled	Netherlands: 5
Country: Number of subjects enrolled	Korea, Republic of: 68
Country: Number of subjects enrolled	Russian Federation: 53

Country: Number of subjects enrolled	Serbia: 11
Country: Number of subjects enrolled	Singapore: 3
Country: Number of subjects enrolled	Spain: 19
Country: Number of subjects enrolled	Sweden: 1
Country: Number of subjects enrolled	Taiwan: 13
Country: Number of subjects enrolled	Thailand: 36
Country: Number of subjects enrolled	United States: 41
Worldwide total number of subjects	402
EEA total number of subjects	102

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)	16
Adults (18-64 years)	381
From 65 to 84 years	5
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 402 participants were enrolled in to the study . 402 Participants were entered the open-label extension of the study, received study drug, and were included in the safety population .

Period 1

Period 1 title	Open-Label Phase (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	Carisbamate less than (<) 400 milligram (mg)

Arm description:

Participants received modal dose of Carisbamate less than 400 milligram (mg) per day

Arm type	Experimental
Investigational medicinal product name	Carisbamate
Investigational medicinal product code	RWJ-333369
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants who received carisbamate less than (<) 400 milligram (mg) in double blind phase .

Investigational medicinal product name	Carisbamate
Investigational medicinal product code	RWJ-333369
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants who received carisbamate less than (<) 400 milligram (mg) in double blind phase

Arm title	Carisbamate 400- less than (<) 600 milligram (mg)

Arm description:

Participants received modal dose of Carisbamate 400 to less than 600 milligram (mg) per day.

Arm type	Experimental
Investigational medicinal product name	Carisbamate
Investigational medicinal product code	RWJ-333369
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants who received carisbamate 400 - less than (<) 600 milligram (mg) in double blind phase.

Arm title	Carisbamate 600-800 milligram (mg)

Arm description:

Participants received modal dose of Carisbamate 600 to 800 milligram (mg) per day.

Arm type	Experimental
Investigational medicinal product name	Carisbamate
Investigational medicinal product code	RWJ-333369
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants who received carisbamate 600 to 800 milligram (mg) in double blind phase.

Arm title	Carisbamate greater than (>) 800-1000 milligram (mg)

Arm description:

Participants received modal dose of Carisbamate greater than 800 to 1000 milligram (mg) per day

Arm type	Experimental
Investigational medicinal product name	carisbamate
Investigational medicinal product code	RWJ-333369
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants who received carisbamate greater than (>) 800-1000 milligram (mg) in double blind phase .

Arm title	Carisbamate greater than (>) 1000-1200 milligram (mg)

Arm description:

Participants received modal dose of Carisbamate greater than 1000 to 1200 milligram (mg) per day

Arm type	Experimental
Investigational medicinal product name	carisbamate
Investigational medicinal product code	RWJ-333369
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Participants who received carisbamate greater than (>) 1000-1200 milligram (mg) in double blind phase .

Number of subjects in period 1	Carisbamate less than (<) 400 milligram (mg)	Carisbamate 400-less than (<) 600 milligram (mg)	Carisbamate 600-800 milligram (mg)
Started	4	32	203
Completed	4	26	167
Not completed	0	6	36
Consent withdrawn by subject	-	2	18
Adverse event, non-fatal	-	3	8
Other	-	-	-
Pregnancy	-	-	-
Lost to follow-up	-	-	2
Lack of efficacy	-	1	8
Protocol deviation	-	-	-

Number of subjects in period 1	Carisbamate greater than (>) 800-1000 milligram (mg)	Carisbamate greater than (>) 1000-1200 milligram (mg)
Started	51	112
Completed	49	94
Not completed	2	18
Consent withdrawn by subject	-	5
Adverse event, non-fatal	-	3
Other	-	1
Pregnancy	-	1
Lost to follow-up	-	-
Lack of efficacy	1	8
Protocol deviation	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Carisbamate less than (<) 400 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate less than 400 milligram (mg) per day	
Reporting group title	Carisbamate 400- less than (<) 600 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate 400 to less than 600 milligram (mg) per day.	
Reporting group title	Carisbamate 600-800 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate 600 to 800 milligram (mg) per day.	

Reporting group title	Carisbamate greater than (>) 800-1000 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate greater than 800 to 1000 milligram (mg) per day	
Reporting group title	Carisbamate greater than (>) 1000-1200 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate greater than 1000 to 1200 milligram (mg) per day	

Reporting group values	Carisbamate less than (<) 400 milligram (mg)	Carisbamate 400- less than (<) 600 milligram (mg)	Carisbamate 600-800 milligram (mg)
Number of subjects	4	32	203
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	1	9
Adults (18-64 years)	4	30	192
From 65 to 84 years	0	1	2
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	38.5	41.3	36.5
standard deviation	± 13.48	± 12.08	± 11.81
Title for Gender Units: subjects			
Female	1	22	103
Male	3	10	100

Reporting group values	Carisbamate greater than (>) 800-1000 milligram (mg)	Carisbamate greater than (>) 1000-1200 milligram (mg)	Total
Number of subjects	51	112	402
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	4	2	16
Adults (18-64 years)	47	108	381

From 65 to 84 years	0	2	5
85 years and over	0	0	0

Title for AgeContinuous Units: years			
arithmetic mean	30.8	36.7	
standard deviation	± 10.82	± 12.04	-
Title for Gender Units: subjects			
Female	23	44	193
Male	28	68	209

End points

End points reporting groups

Reporting group title	Carisbamate less than (<) 400 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate less than 400 milligram (mg) per day	
Reporting group title	Carisbamate 400- less than (<) 600 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate 400 to less than 600 milligram (mg) per day.	
Reporting group title	Carisbamate 600-800 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate 600 to 800 milligram (mg) per day.	

Reporting group title	Carisbamate greater than (>) 800-1000 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate greater than 800 to 1000 milligram (mg) per day	
Reporting group title	Carisbamate greater than (>) 1000-1200 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate greater than 1000 to 1200 milligram (mg) per day	
Subject analysis set title	Intent-to-treat
Subject analysis set type	Per protocol
Subject analysis set description:	
A total of 402 Participants were included in the intent to treat (ITT) analysis	

Primary: Percentage Change From Baseline to the Open Label (OL) Phase in partial onset seizures (POS) Frequency

End point title	Percentage Change From Baseline to the Open Label (OL) Phase in partial onset seizures (POS) Frequency[1]
End point description:	
Percentage change in seizure frequency was calculated as 100 * (pre-treatment seizures minus Maintenance Phase seizures)/pre-treatment seizures. Partial Onset seizures are seizures that affect only a part of the brain at onset.	
End point type	Primary
End point timeframe:	
Baseline (Day 1 of study CARISEPY3013) up to 1 year (end of open-label phase)	

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			
Subject group type	Subject analysis set			
Number of subjects analysed	402			
Units: Percentage				
median (full range (min-max))				
Change from Baseline	28.22 (-865.52 to 100)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With at Least a 50 Percent Reduction in Seizure Frequency

End point title	Percentage of Participants With at Least a 50 Percent Reduction in Seizure Frequency[2]

End point description:

Responders were defined as Participants who had at least a 50% reduction in monthly seizure rate from baseline.

End point type	Primary

End point timeframe:

Baseline (Day 1 of study CARISEPY3013) up to 1 year (end of open-label phase)

Notes:

[2] - 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			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: Percentage				
number (not applicable)	36.1			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage Reduction From Baseline to the Last 6 Months of the Open Label (OL) Phase in Partial Onset Seizure (POS) Frequency

End point title	Percentage Reduction From Baseline to the Last 6 Months of the Open Label (OL) Phase in Partial Onset Seizure (POS) Frequency[3]

End point description:

The Percentage reduction in seizure rate relative to baseline was calculated for the period preceding the final 2 visits for each participant (about 6 months for most participants).

End point type	Primary

End point timeframe:

Month 6-12

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			
Subject group type	Subject analysis set			
Number of subjects analysed				
Units: Percentage				
median (full range (min-max))	37.35 (-174.2 to 100)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Seizure-Free Rate of the Open Label (OL) Phase in Partial Onset Seizure (POS)

End point title	Percentage of Participants With Seizure-Free Rate of the Open Label (OL) Phase in Partial Onset Seizure (POS)[4]

End point description:

Percentage of Participants who are free from seizures.

End point type	Primary

End point timeframe:

Month 6-12

Notes:

[4] - 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			
Subject group type	Subject analysis set			
Number of subjects analysed	368			
Units: Percentage				
number (not applicable)	5.4			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Serious Adverse Events (SAEs)

End point title	Number of Participants With Serious Adverse Events (SAEs)[5]

End point description:

An Serious Adverse Event (SAE) was an Adverse Event (AE) resulting in any of the following outcomes or deemed significant for any other reason: death; initial or prolonged in-patient hospitalization; life-threatening experience (immediate risk of dying); persistent or significant disability/incapacity; congenital anomaly.

End point type	Primary

End point timeframe:

Baseline (Day 1 of study CARISEPY3013) up to 1 year (end of open-label phase)

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	Carisbamate less than (<) 400 milligram (mg)	Carisbamate 400- less than (<) 600 milligram (mg)	Carisbamate 600-800 milligram (mg)	Carisbamate greater than (>) 800-1000 milligram (mg)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	32	203	51
Units: Percentage				
number (not applicable)	0	5	12	3

End point values	Carisbamate greater than (>) 1000-1200 milligram (mg)			
Subject group type	Reporting group			
Number of subjects analysed	112			
Units: Percentage				
number (not applicable)	8			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Baseline (Day 1 of study CARISEPY3013) up to 1 year (end of open-label phase)	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	12.1
Reporting groups	
Reporting group title	Carisbamate less than (<) 400 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate less than 400 milligram (mg) per day.	
Reporting group title	Carisbamate 400 - less than (<) 600 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate 400 to less than 600 milligram (mg)per day	
Reporting group title	Carisbamate 600-800 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate 600 to 800 milligram (mg) per day	
Reporting group title	Carisbamate greater than (>) 800-1000 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate greater than 800 to 1000 greater than per day	
Reporting group title	Carisbamate greater than (>) 1000-1200 milligram (mg)
Reporting group description:	
Participants received modal dose of Carisbamate greater than 1000 to 1200 milligram (mg) per day	

Serious adverse events	Carisbamate less than (<) 400 milligram (mg)	Carisbamate 400 - less than (<) 600 milligram (mg)	Carisbamate 600-800 milligram (mg)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	5 / 32 (15.63%)	12 / 203 (5.91%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer metastatic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Vascular disorders			
Phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Sudden unexplained death in epilepsy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (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
Delirium			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (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
Psychotic disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			

Investigation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (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
Jaw fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper limb fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
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			
Convulsion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	3 / 203 (1.48%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (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
Epilepsy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Partial seizures with secondary generalisation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sensory disturbance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
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 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (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
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
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			
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia oral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatitis toxic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Drug rash with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Systemic lupus erythematosus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
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			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Carisbamate greater than (>) 800-1000 milligram (mg)	Carisbamate greater than (>) 1000-1200 milligram (mg)	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 51 (5.88%)	8 / 112 (7.14%)	
number of deaths (all causes)	1	1	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer metastatic			

subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Phlebitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Sudden unexplained death in epilepsy			
subjects affected / exposed	1 / 51 (1.96%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 51 (1.96%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			

subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychotic disorder			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Investigation			
subjects affected / exposed	0 / 51 (0.00%)	2 / 112 (1.79%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw fracture			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Convulsion			
subjects affected / exposed	1 / 51 (1.96%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Epilepsy			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial seizures with secondary generalisation			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sensory disturbance			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postictal state			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Hypoaesthesia oral			
subjects affected / exposed	1 / 51 (1.96%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatitis toxic			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Drug rash with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Systemic lupus erythematosus			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			

subjects affected / exposed	1 / 51 (1.96%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Carisbamate less than (<) 400 milligram (mg)	Carisbamate 400 - less than (<) 600 milligram (mg)	Carisbamate 600-800 milligram (mg)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 4 (75.00%)	28 / 32 (87.50%)	114 / 203 (56.16%)
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	6 / 203 (2.96%)
occurrences (all)	0	1	14
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	2 / 32 (6.25%)	1 / 203 (0.49%)
occurrences (all)	0	2	1
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	3 / 203 (1.48%)
occurrences (all)	0	1	4
Fatigue			
subjects affected / exposed	1 / 4 (25.00%)	3 / 32 (9.38%)	12 / 203 (5.91%)
occurrences (all)	2	3	13
Influenza like illness			
subjects affected / exposed	1 / 4 (25.00%)	1 / 32 (3.13%)	2 / 203 (0.99%)
occurrences (all)	1	1	2
Pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	2 / 203 (0.99%)
occurrences (all)	0	4	3
Irritability			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	4 / 203 (1.97%)
occurrences (all)	0	1	4
Pyrexia			

subjects affected / exposed	1 / 4 (25.00%)	2 / 32 (6.25%)	3 / 203 (1.48%)
occurrences (all)	1	2	6
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	2 / 203 (0.99%)
occurrences (all)	0	1	3
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	2 / 32 (6.25%)	5 / 203 (2.46%)
occurrences (all)	0	2	8
Dysphoria			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	1 / 203 (0.49%)
occurrences (all)	0	1	1
Emotional disorder			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	8 / 203 (3.94%)
occurrences (all)	0	0	10
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	2 / 203 (0.99%)
occurrences (all)	0	0	2
Tandem gait test abnormal			
subjects affected / exposed	1 / 4 (25.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences (all)	1	0	0

Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	2 / 203 (0.99%)
occurrences (all)	0	0	2
Injury, poisoning and procedural complications			
Face injury			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	1 / 203 (0.49%)
occurrences (all)	0	1	1
Medication error			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	3 / 203 (1.48%)
occurrences (all)	0	1	3
Joint sprain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	3 / 203 (1.48%)
occurrences (all)	0	1	3
Mouth injury			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	3 / 203 (1.48%)
occurrences (all)	0	1	3
Nail avulsion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Open wound			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Skin laceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Ataxia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	3 / 203 (1.48%)
occurrences (all)	0	0	3
Convulsion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	8 / 203 (3.94%)
occurrences (all)	0	0	10
Disturbance in attention			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	8 / 203 (3.94%)
occurrences (all)	0	1	8
Dizziness			
subjects affected / exposed	2 / 4 (50.00%)	13 / 32 (40.63%)	29 / 203 (14.29%)
occurrences (all)	2	17	46
Dysaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	2 / 203 (0.99%)
occurrences (all)	0	1	2
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	9 / 32 (28.13%)	31 / 203 (15.27%)
occurrences (all)	0	11	71
Postictal headache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	1 / 203 (0.49%)
occurrences (all)	0	1	1
Nystagmus			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	1 / 203 (0.49%)
occurrences (all)	0	1	1
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	3 / 203 (1.48%)
occurrences (all)	0	1	3
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	6 / 32 (18.75%)	20 / 203 (9.85%)
occurrences (all)	0	6	23
Tension headache			

subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	2 / 32 (6.25%)	1 / 203 (0.49%)
occurrences (all)	0	2	1
Blood and lymphatic system disorders			
Eosinophilia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	1 / 203 (0.49%)
occurrences (all)	0	1	1
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Hyperacusis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	1 / 203 (0.49%)
occurrences (all)	0	1	1
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	3 / 32 (9.38%)	10 / 203 (4.93%)
occurrences (all)	0	8	12
Eye disorders			
Vision blurred			
subjects affected / exposed	1 / 4 (25.00%)	0 / 32 (0.00%)	4 / 203 (1.97%)
occurrences (all)	1	0	5
Visual impairment			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	2 / 203 (0.99%)
occurrences (all)	0	1	2
Diplopia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 32 (0.00%)	4 / 203 (1.97%)
occurrences (all)	2	0	7
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	3 / 203 (1.48%)
occurrences (all)	0	1	3
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	1 / 203 (0.49%)
occurrences (all)	0	1	2
Constipation			

subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	2 / 203 (0.99%)
occurrences (all)	0	1	2
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	2 / 203 (0.99%)
occurrences (all)	0	1	3
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	2 / 32 (6.25%)	9 / 203 (4.43%)
occurrences (all)	0	2	10
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	2 / 32 (6.25%)	19 / 203 (9.36%)
occurrences (all)	0	4	35
Hypoaesthesia oral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	1 / 203 (0.49%)
occurrences (all)	0	1	2
Ileus paralytic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Paraesthesia oral			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	1 / 203 (0.49%)
occurrences (all)	0	1	1
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	1 / 203 (0.49%)
occurrences (all)	0	1	1
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	3 / 32 (9.38%)	11 / 203 (5.42%)
occurrences (all)	0	5	22
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	2 / 203 (0.99%)
occurrences (all)	0	1	2
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences (all)	0	0	0

Skin lesion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Nocturia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Urine abnormality			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	1 / 203 (0.49%)
occurrences (all)	0	1	1
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Cellulitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	3 / 32 (9.38%)	6 / 203 (2.96%)
occurrences (all)	0	4	6
Nasopharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	13 / 203 (6.40%)
occurrences (all)	0	1	16

Systemic candida			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	4 / 203 (1.97%)
occurrences (all)	0	1	6
Upper respiratory tract infection			
subjects affected / exposed	1 / 4 (25.00%)	1 / 32 (3.13%)	6 / 203 (2.96%)
occurrences (all)	1	3	7
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	1 / 32 (3.13%)	5 / 203 (2.46%)
occurrences (all)	1	2	5

Non-serious adverse events	Carisbamate greater than (>) 800-1000 milligram (mg)	Carisbamate greater than (>) 1000-1200 milligram (mg)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	35 / 51 (68.63%)	63 / 112 (56.25%)	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 51 (3.92%)	1 / 112 (0.89%)	
occurrences (all)	2	1	
Chest pain			
subjects affected / exposed	2 / 51 (3.92%)	1 / 112 (0.89%)	
occurrences (all)	3	1	
Chills			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences (all)	0	1	
Chest discomfort			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Gait disturbance			
subjects affected / exposed	1 / 51 (1.96%)	1 / 112 (0.89%)	
occurrences (all)	1	1	
Fatigue			

subjects affected / exposed	5 / 51 (9.80%)	5 / 112 (4.46%)	
occurrences (all)	5	6	
Influenza like illness			
subjects affected / exposed	0 / 51 (0.00%)	2 / 112 (1.79%)	
occurrences (all)	0	2	
Pain			
subjects affected / exposed	0 / 51 (0.00%)	2 / 112 (1.79%)	
occurrences (all)	0	3	
Malaise			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Irritability			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences (all)	0	1	
Pyrexia			
subjects affected / exposed	2 / 51 (3.92%)	5 / 112 (4.46%)	
occurrences (all)	2	7	
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 51 (3.92%)	1 / 112 (0.89%)	
occurrences (all)	2	2	
Rhinorrhoea			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences (all)	0	1	
Dysphoria			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Depression			

subjects affected / exposed	1 / 51 (1.96%)	0 / 112 (0.00%)	
occurrences (all)	1	0	
Emotional disorder			
subjects affected / exposed	1 / 51 (1.96%)	1 / 112 (0.89%)	
occurrences (all)	1	1	
Insomnia			
subjects affected / exposed	0 / 51 (0.00%)	7 / 112 (6.25%)	
occurrences (all)	0	11	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 51 (3.92%)	1 / 112 (0.89%)	
occurrences (all)	2	1	
Tandem gait test abnormal			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 51 (3.92%)	0 / 112 (0.00%)	
occurrences (all)	2	0	
Injury, poisoning and procedural complications			
Face injury			
subjects affected / exposed	1 / 51 (1.96%)	0 / 112 (0.00%)	
occurrences (all)	1	0	
Medication error			
subjects affected / exposed	1 / 51 (1.96%)	3 / 112 (2.68%)	
occurrences (all)	3	4	
Joint sprain			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences (all)	0	1	
Mouth injury			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences (all)	0	1	
Nail avulsion			

subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Open wound			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Skin laceration			
subjects affected / exposed	2 / 51 (3.92%)	1 / 112 (0.89%)	
occurrences (all)	2	1	
Rib fracture			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Ataxia			
subjects affected / exposed	0 / 51 (0.00%)	4 / 112 (3.57%)	
occurrences (all)	0	4	
Convulsion			
subjects affected / exposed	1 / 51 (1.96%)	1 / 112 (0.89%)	
occurrences (all)	1	1	
Disturbance in attention			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Dizziness			
subjects affected / exposed	22 / 51 (43.14%)	25 / 112 (22.32%)	
occurrences (all)	32	32	
Dysaesthesia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Hypoaesthesia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Lethargy			
subjects affected / exposed	1 / 51 (1.96%)	0 / 112 (0.00%)	
occurrences (all)	1	0	

Headache			
subjects affected / exposed	8 / 51 (15.69%)	16 / 112 (14.29%)	
occurrences (all)	23	50	
Postictal headache			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Nystagmus			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences (all)	0	1	
Memory impairment			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences (all)	0	1	
Somnolence			
subjects affected / exposed	4 / 51 (7.84%)	7 / 112 (6.25%)	
occurrences (all)	4	7	
Tension headache			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences (all)	0	1	
Blood and lymphatic system disorders			
Eosinophilia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Hyperacusis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences (all)	0	1	
Eye disorders			

Vision blurred			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences (all)	0	1	
Visual impairment			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Diplopia			
subjects affected / exposed	4 / 51 (7.84%)	9 / 112 (8.04%)	
occurrences (all)	7	20	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 51 (1.96%)	1 / 112 (0.89%)	
occurrences (all)	1	1	
Colitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	1 / 51 (1.96%)	0 / 112 (0.00%)	
occurrences (all)	1	0	
Dyspepsia			
subjects affected / exposed	1 / 51 (1.96%)	2 / 112 (1.79%)	
occurrences (all)	1	2	
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	2 / 51 (3.92%)	4 / 112 (3.57%)	
occurrences (all)	2	4	
Nausea			
subjects affected / exposed	2 / 51 (3.92%)	8 / 112 (7.14%)	
occurrences (all)	3	8	
Hypoaesthesia oral			
subjects affected / exposed	1 / 51 (1.96%)	1 / 112 (0.89%)	
occurrences (all)	2	1	
Ileus paralytic			

subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Paraesthesia oral			
subjects affected / exposed	1 / 51 (1.96%)	0 / 112 (0.00%)	
occurrences (all)	1	0	
Rectal haemorrhage			
subjects affected / exposed	1 / 51 (1.96%)	0 / 112 (0.00%)	
occurrences (all)	1	0	
Vomiting			
subjects affected / exposed	3 / 51 (5.88%)	6 / 112 (5.36%)	
occurrences (all)	3	6	
Toothache			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	2 / 51 (3.92%)	0 / 112 (0.00%)	
occurrences (all)	3	0	
Skin lesion			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences (all)	0	1	
Renal and urinary disorders			
Nocturia			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Urine abnormality			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 51 (3.92%)	2 / 112 (1.79%)	
occurrences (all)	3	2	
Muscular weakness			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal chest pain			

subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal pain			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Abscess			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Cellulitis			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	1 / 51 (1.96%)	3 / 112 (2.68%)	
occurrences (all)	1	3	
Nasopharyngitis			
subjects affected / exposed	6 / 51 (11.76%)	11 / 112 (9.82%)	
occurrences (all)	10	13	
Systemic candida			
subjects affected / exposed	0 / 51 (0.00%)	0 / 112 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 51 (0.00%)	1 / 112 (0.89%)	
occurrences (all)	0	1	
Upper respiratory tract infection			
subjects affected / exposed	2 / 51 (3.92%)	2 / 112 (1.79%)	
occurrences (all)	2	4	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 51 (0.00%)	3 / 112 (2.68%)	
occurrences (all)	0	3	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 February 2009	The overall reason for the amendment was to include the following changes: 1) suspected transmission of an infectious agent by a medicinal product was considered a serious adverse event. 2) clarifications were made to the Prohibitions and Restrictions,3) To specify that Participants who could tolerate the dosage during the first week of the titration period,4) The sections on Laboratory Tests, and ECG collection, were clarified,5) The statistical step-down procedure was modified for both the primary and secondary efficacy endpoints.
22 September 2009	The overall reason for the amendment was to include the update withdrawal criteria.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

There were no discernible trends in the Quality of Life in Epilepsy-31 (QOLIE-31) data across modal treatment groups.

Notes: