Clinical trial results:
A Study of the Effectiveness, Safety, and Tolerability of Carisbamate as Add-On Therapy in Patients With Partial Onset Seizures. Followed by an Open-Label Extension Study of the Safety and Tolerability of Carisbamate as Add-On Therapy in Patients With Partial Onset Seizures

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

Summary

EudraCT number	2008-005098-37
Trial protocol	BE FI DE SE NL ES IT
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	06 August 2015
Version creation reason	• Correction of full data set Review of data

Trial information

Trial identification

Sponsor protocol code	CARISEPY3013/CARISEPY3014

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Janssen Cilag International, NV
Sponsor organisation address	Archimedsweg 29-2333CM, Leiden, Netherlands,
Public contact	Clinical Registry Group, Clinical Registry Group, 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?	No

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 purpose of this study (CARISEPY3013) was to evaluate the effectiveness, safety, and tolerability of carisbamate as add-on therapy for the treatment of partial onset seizures in patients with epilepsy.

The Primary objective of this study study (CARISEPY3014) was to provide long-term safety and tolerability information on carisbamate as add-on therapy for the treatment of partial onset seizures in subjects 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	07 November 2008
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	Australia: 22
Country: Number of subjects enrolled	Belgium: 13
Country: Number of subjects enrolled	Croatia: 12
Country: Number of subjects enrolled	Finland: 8
Country: Number of subjects enrolled	Germany: 31
Country: Number of subjects enrolled	Hong Kong: 15
Country: Number of subjects enrolled	India: 49
Country: Number of subjects enrolled	Italy: 31
Country: Number of subjects enrolled	Lithuania: 12
Country: Number of subjects enrolled	Mexico: 21
Country: Number of subjects enrolled	Netherlands: 5
Country: Number of subjects enrolled	Korea, Republic of: 93
Country: Number of subjects enrolled	Russian Federation: 68

Country: Number of subjects enrolled	Serbia: 12
Country: Number of subjects enrolled	Singapore: 8
Country: Number of subjects enrolled	Spain: 25
Country: Number of subjects enrolled	Sweden: 5
Country: Number of subjects enrolled	Taiwan: 28
Country: Number of subjects enrolled	Thailand: 37
Country: Number of subjects enrolled	United States: 52
Worldwide total number of subjects	547
EEA total number of subjects	142

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)	19
Adults (18-64 years)	518
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

547 subjects were assigned into 3 groups in a 1:1:1 ratio to receive either 800 milligram per day [mg/day] carisbamate, 1,200 mg/day carisbamate, or placebo for 14 weeks in Phase 1 of study and Total of 402 Subjects were enrolled into the Phase 2 (open-label extension) of the study, received study drug, and were included in the safety population

Period 1

Period 1 title	Double-Blind Treatment (Day 1 to 99)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Matching placebo to carisbamate [CRS] for 14 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Film-coated tablet
Routes of administration	Oral use

Dosage and administration details:

Placebo for 14 weeks

Arm title	Carisbamate [CRS] 800 mg

Arm description:

In Week 1 of the titration period, the dosage of carisbamate was 400 milligram per day [mg/day], and in Week 2 to 14, the dosage was increase to 800 mg/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:

In Week 1 of the titration period, the dosage of carisbamate was 400 milligram per day [mg/day], and in Week 2 to 14, the dosage was increase to 800 mg/day.

Arm title	Carisbamate [CRS] 1200 mg

Arm description:

In Week 1 of the titration period, the dosage of carisbamate was 400 milligram per day [mg/day],and in Week 2 the dosage was increase to 800 mg/day. In Weeks 3 to 14 of the maintenance period, dosage increased to 1,200 mg/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:

In Week 1 of the titration period, the dosage of carisbamate was 400 milligram per day [mg/day], and in Week 2 the dosage was increase to 800 mg/day. In Weeks 3 to 14 of the maintenance period, dosage increased to 1,200 mg/day.

Number of subjects in period 1	Placebo	Carisbamate [CRS] 800 mg	Carisbamate [CRS] 1200 mg
Started	185	180	182
Completed	164	144	126
Not completed	21	36	56
Consent withdrawn by subject	5	9	9
Adverse event, non-fatal	6	14	30
Other	5	3	6
Adverse event, serious non-fatal	1	3	5
Lost to follow-up	2	1	1
Protocol deviation	2	5	4
Lack of efficacy	-	1	1

Period 2

Period 2 title	Open-Label Phase
Is this the baseline period?	No
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	Carisbamate less than (<) 400 milligram (mg)

Arm description:

subjects 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:

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

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

Arm description:
subjects 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:
subjects who received carisbamate 400 - less than (<) 600 milligram (mg) in double blind phase.

Arm title	Carisbamate 600-800 milligram (mg)

Arm description:
Subjects 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:
subjects who received carisbamate 600 to 800 milligram (mg) in double blind phase.

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

Arm description:
subjects 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:
subjects who received carisbamate greater than (>) 800-1000 milligram (mg) in double blind phase .

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

Arm description:
subjects 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:
subjects who received carisbamate greater than (>) 1000-1200 milligram (mg) in double blind phase

Number of subjects in period 2	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 2	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	Placebo
Reporting group description:	
Matching placebo to carisbamate [CRS] for 14 weeks.	
Reporting group title	Carisbamate [CRS] 800 mg
Reporting group description:	
In Week 1 of the titration period, the dosage of carisbamate was 400 milligram per day [mg/day], and in Week 2 to 14, the dosage was increase to 800 mg/day.	
Reporting group title	Carisbamate [CRS] 1200 mg
Reporting group description:	
In Week 1 of the titration period, the dosage of carisbamate was 400 milligram per day [mg/day],and in Week 2 the dosage was increase to 800 mg/day. In Weeks 3 to 14 of the maintenance period, dosage increased to 1,200 mg/day.	

Reporting group values	Placebo	Carisbamate [CRS] 800 mg	Carisbamate [CRS] 1200 mg
Number of subjects	185	180	182
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	4	6	9
Adults (18-64 years)	177	171	170
From 65 to 84 years	4	3	3
85 years and over	0	0	0
Title for AgeContinuous Units: years			
arithmetic mean	36.6	36.8	36.8
standard deviation	± 12.18	± 12.02	± 12.53
Title for Gender Units: subjects			
Female	96	92	90
Male	89	88	92

Reporting group values	Total		
Number of subjects	547		
Title for AgeCategorical Units: subjects			
Children (2-11 years)	0		
Adolescents (12-17 years)	19		
Adults (18-64 years)	518		
From 65 to 84 years	10		
85 years and over	0		
Title for AgeContinuous Units: years			
arithmetic mean			
standard deviation	-		

Title for Gender Units: subjects			
Female	278		
Male	269		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Matching placebo to carisbamate [CRS] for 14 weeks.	
Reporting group title	Carisbamate [CRS] 800 mg
Reporting group description:	
In Week 1 of the titration period, the dosage of carisbamate was 400 milligram per day [mg/day], and in Week 2 to 14, the dosage was increase to 800 mg/day.	
Reporting group title	Carisbamate [CRS] 1200 mg
Reporting group description:	
In Week 1 of the titration period, the dosage of carisbamate was 400 milligram per day [mg/day],and in Week 2 the dosage was increase to 800 mg/day. In Weeks 3 to 14 of the maintenance period, dosage increased to 1,200 mg/day.	
Reporting group title	Carisbamate less than (<) 400 milligram (mg)
Reporting group description:	
subjects 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:	
subjects 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:	
Subjects 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:	
subjects 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:	
subjects received modal dose of Carisbamate greater than 1000 to 1200 milligram (mg) per day	
Subject analysis set title	Intent-to-treat (ITT) population
Subject analysis set type	Intention-to-treat
Subject analysis set description:	
A total of 402 subjects were included in the intent to treat (ITT) analysis in study CARISEPY3014	

Primary: Percent Reduction From Baseline in partial onset Seizure Frequency

End point title	Percent Reduction From Baseline in partial onset Seizure Frequency
End point description:	
The primary efficacy endpoint was the percent reduction in partial onset seizure frequency (average seizure rate per 28 days of all simple partial motor, complex partial, or secondarily generalized seizures) from the baseline phase relative to the entire double-blind treatment phase. The frequency of seizures was calculated by the actual seizure count multiplied by 28, divided by the number of days in the phase; in effect, frequency count was normalized to 28 days.	
End point type	Primary
End point timeframe:	
Baseline up to end of double-blind treatment phase (week 14)	

End point values	Placebo	Carisbamate [CRS] 800 mg	Carisbamate [CRS] 1200 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	183[1]	176[2]	181[3]	
Units: percent change				
median (full range (min-max))	20.59 (-576 to 100)	29.93 (-1981 to 100)	36.3 (-140 to 100)	

Notes:

[1] - ITT population

[2] - ITT Population

[3] - ITT population

Statistical analyses

Statistical analysis title	Statistical analysis 1
Comparison groups	Placebo v Carisbamate [CRS] 800 mg
Number of subjects included in analysis	359
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.903 [4]
Method	Wilcoxon rank sum test controlling

Notes:

[4] - P-values from Wilcoxon rank sum test controlling for pooled country and enzyme induction group based on IVRS value.

Statistical analysis title	Statistical analysis 2
Comparison groups	Carisbamate [CRS] 1200 mg v Placebo
Number of subjects included in analysis	364
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.041 [5]
Method	Wilcoxon rank sum test controlling

Notes:

[5] - P-values from Wilcoxon rank sum test controlling for pooled country and enzyme induction group based on IVRS value.

Primary: Number of subjects With greater or equal to 50% reduction in POS frequency from baseline (Responder Rate)

End point title	Number of subjects With greater or equal to 50% reduction in POS frequency from baseline (Responder Rate)

End point description:

End point type	Primary

End point timeframe:

From baseline relative to the entire double-blind treatment phase (14 weeks)

End point values	Placebo	Carisbamate [CRS] 800 mg	Carisbamate [CRS] 1200 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	183[6]	176[7]	181[8]	
Units: Number of participants				
number (not applicable)	48	49	66	

Notes:

[6] - ITT Population

[7] - ITT Population

[8] - ITT population

Statistical analyses

Statistical analysis title	Statistical analysis 3
Comparison groups	Placebo v Carisbamate [CRS] 800 mg
Number of subjects included in analysis	359
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.792
Method	Cochran-Mantel-Haenszel
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.58
upper limit	10.8

Statistical analysis title	Statistical analysis 4
Comparison groups	Carisbamate [CRS] 1200 mg v Placebo
Number of subjects included in analysis	364
Analysis specification	Pre-specified
Analysis type	equivalence
P-value	= 0.043
Method	Cochran-Mantel-Haenszel
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	19.71

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[9]

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:

[9] - 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	402[10]			
Units: Percentage				
median (full range (min-max))	28.22 (-865.52 to 100)			

Notes:

[10] - ITT Population

Statistical analyses

No statistical analyses for this end point

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

End point title	Percentage of subjects With at Least a 50 Percent Reduction in Seizure Frequency[11]

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:

[11] - 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				
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[12]

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:

[12] - 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				
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 subjects With Seizure-Free Rate of the Open Label (OL) Phase in Partial Onset Seizure (POS)

End point title	Percentage of subjects With Seizure-Free Rate of the Open Label (OL) Phase in Partial Onset Seizure (POS)[13]

End point description:

Percentage of Participants who are free from seizures.

End point type	Primary

End point timeframe:

Month 6-12

Notes:

[13] - 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	368			
Units: Percentage				
number (not applicable)	5.4			

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of subjects With Serious Adverse Events (SAEs)[14]

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:

[14] - 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

Secondary: Percent Reduction from baseline in Secondarily Generalized Seizure Frequency

End point title	Percent Reduction from baseline in Secondarily Generalized Seizure Frequency

End point description:

Change in secondary generalized seizure frequency is given as a percent reduction computed as: [Weekly sec. generalized seizure frequency (Baseline)- Weekly sec. generalized seizure frequency (Evaluation Period)]/ [Weekly sec. generalized seizure frequency (Baseline)] x 100. Positive values in reduction means the value decreased from Baseline during the first 16-week Period. "Number of participants Analyzed = number of participants who were evaluable for this outcome measure"

End point type	Secondary

End point timeframe:

Baseline up to double-blind treatment phase (14 weeks)

End point values	Placebo	Carisbamate [CRS] 800 mg	Carisbamate [CRS] 1200 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	78	65	81	
Units: Number of participants				
median (full range (min-max))	11.2 (-800 to 100)	6.7 (-800 to 100)	40 (-800 to 100)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time of Onset of Treatment Effect on partial onset seizure frequency reduction

End point title	Time of Onset of Treatment Effect on partial onset seizure frequency reduction

End point description:

Participant's perception of treatment response assessment since the previous visit was noted at each visit. Time to onset of response was calculated in weeks from start of treatment.

End point type	Secondary

End point timeframe:

From baseline relative to the entire double-blind treatment phase (14 weeks)

End point values	Placebo	Carisbamate [CRS] 800 mg	Carisbamate [CRS] 1200 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	183	176	181	
Units: Number of Subjects				
median (full range (min-max))	20.97 (-576 to 100)	30.01 (-1981 to 100)	36.26 (-140 to 100)	

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:	
subjects 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:	
subjects 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:	
Subjects received modal dose of Carisbamate 600 to 800 milligram (mg) per day.	
Reporting group title	Carisbamate greater than (>) 1000-1200 milligram (mg)
Reporting group description:	
subjects received modal dose of Carisbamate greater than 1000 to 1200 milligram (mg) per day	
Reporting group title	Carisbamate greater than (>) 800-1000 milligram (mg)
Reporting group description:	
subjects received modal dose of Carisbamate greater than 800 to 1000 milligram (mg) per day	
Reporting group title	Placebo
Reporting group description:	
Matching placebo to carisbamate [CRS] for 14 weeks.	
Reporting group title	Carisbamate [CRS] 800 mg
Reporting group description:	
In Week 1 of the titration period, the dosage of carisbamate was 400 milligram per day [mg/day], and in Week 2 to 14, the dosage was increase to 800 mg/day.	
Reporting group title	Carisbamate [CRS] 1200 mg
Reporting group description:	
In Week 1 of the titration period, the dosage of carisbamate was 400 milligram per day [mg/day],and in Week 2 the dosage was increase to 800 mg/day. In Weeks 3 to 14 of the maintenance period, dosage increased to 1,200 mg/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	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Ovarian Epithelial Cancer Metastatic			
alternative assessment type: Systematic			
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
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
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
alternative assessment type: Systematic			
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
General disorders and administration site conditions			
Asthenia			
alternative assessment type: Systematic			
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
Non-Cardiac Chest Pain			
alternative assessment type: Systematic			

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
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
Reproductive system and breast disorders			
Ovarian Cyst			
alternative assessment type: Systematic			
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			
Anxiety			
alternative assessment type: Systematic			
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
Psychotic Disorder			
alternative assessment type: Systematic			
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

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
Investigations			
Alanine Aminotransferase Increased			
alternative assessment type: Systematic			
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
Aspartate Aminotransferase Increased			
alternative assessment type: Systematic			
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
Liver Function Test Abnormal			
alternative assessment type: Systematic			
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
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			
Intentional Overdose			
alternative assessment type: Systematic			

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
Wrist Fracture			
alternative assessment type: Systematic			
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
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%)	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
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			
Ataxia			
alternative assessment type: Systematic			
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
Balance Disorder			
alternative assessment type: Systematic			
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
Cerebral Infarction			
alternative assessment type: Systematic			

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
Cervical Root Pain			
alternative assessment type: Systematic			
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
Convulsion			
alternative assessment type: Systematic			
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			
alternative assessment type: Systematic			
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
Drug Withdrawal Convulsions			
alternative assessment type: Systematic			
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
Epilepsy			
alternative assessment type: Systematic			
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			
alternative assessment type: Systematic			
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

Lethargy			
alternative assessment type: Systematic			
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
Partial Seizures with Secondary Generalisation			
alternative assessment type: Systematic			
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
Somnolence			
alternative assessment type: Systematic			
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
Syncope			
alternative assessment type: Systematic			
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
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
Blood and lymphatic system disorders			
Anaemia			
alternative assessment type: Systematic			

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
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
Eye disorders			
Diplopia			
alternative assessment type: Systematic			
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
Gastrointestinal disorders			
Abdominal Pain Upper			
alternative assessment type: Systematic			
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
Colitis			
alternative assessment type: Systematic			
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 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
alternative assessment type: Systematic			
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
Food Poisoning			
alternative assessment type: Systematic			

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
Nausea			
alternative assessment type: Systematic			
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
Pancreatitis Acute			
alternative assessment type: Systematic			
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			
alternative assessment type: Systematic			
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 / 0
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
Hepatobiliary disorders			
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
Hepatobiliary disorders			
Bile Duct Stone			
alternative assessment type: Systematic			
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
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			
alternative assessment type: Systematic			
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
Gastroenteritis			
alternative assessment type: Systematic			
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
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
Metabolism and nutrition disorders			
Decreased Appetite			
alternative assessment type: Systematic			
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
Hyponatraemia			
alternative assessment type: Systematic			
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
Hypophagia			
alternative assessment type: Systematic			
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

Serious adverse events	Carisbamate greater than (>) 1000-1200 milligram (mg)	Carisbamate greater than (>) 800-1000 milligram (mg)	Placebo

Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 112 (7.14%)	3 / 51 (5.88%)	6 / 184 (3.26%)
number of deaths (all causes)	1	1	0
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ovarian Epithelial Cancer Metastatic			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Breast cancer metastatic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Lung neoplasm malignant			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (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
Vascular disorders			
Phlebitis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
General disorders and administration site conditions			
Asthenia			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Non-Cardiac Chest Pain			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Sudden unexplained death in epilepsy			
subjects affected / exposed	0 / 112 (0.00%)	1 / 51 (1.96%)	0 / 184 (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
Death			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (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
Reproductive system and breast disorders			
Ovarian Cyst			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	1 / 184 (0.54%)
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			
Dyspnoea			
subjects affected / exposed	0 / 112 (0.00%)	1 / 51 (1.96%)	0 / 184 (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
Psychiatric disorders			
Anxiety			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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

Psychotic Disorder			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Confusional state			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Delirium			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Investigations			
Alanine Aminotransferase Increased			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Aspartate Aminotransferase Increased			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Liver Function Test Abnormal			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Investigation			
subjects affected / exposed	2 / 112 (1.79%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Intentional Overdose			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Wrist Fracture			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	1 / 184 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Jaw fracture			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ataxia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Balance Disorder			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Cerebral Infarction			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	1 / 184 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical Root Pain			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Convulsion			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	1 / 51 (1.96%)	0 / 184 (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
Dizziness			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Drug Withdrawal Convulsions			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Epilepsy			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 112 (0.89%)	1 / 51 (1.96%)	1 / 184 (0.54%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Headache			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Lethargy			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Partial Seizures with Secondary Generalisation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	1 / 184 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Syncope			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Sensory disturbance			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Postictal state			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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

Blood and lymphatic system disorders			
Anaemia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Febrile neutropenia			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Eye disorders			
Diplopia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Gastrointestinal disorders			
Abdominal Pain Upper			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Colitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Food Poisoning			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Nausea			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Pancreatitis Acute			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Hypoaesthesia oral			
subjects affected / exposed	0 / 112 (0.00%)	1 / 51 (1.96%)	0 / 184 (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
Hepatobiliary disorders			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile Duct Stone			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Drug rash with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Musculoskeletal and connective tissue disorders			
Systemic lupus erythematosus			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (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
Infections and infestations			
Bronchitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (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
Gastroenteritis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	1 / 51 (1.96%)	1 / 184 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (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
Pneumonia bacterial			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (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
Sepsis			

subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (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
Pneumonia viral			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (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
Subcutaneous abscess			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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 respiratory tract infection			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Metabolism and nutrition disorders			
Decreased Appetite			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Hyponatraemia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (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
Hypophagia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Carisbamate [CRS] 800 mg	Carisbamate [CRS] 1200 mg	
Total subjects affected by serious			

adverse events			
subjects affected / exposed	9 / 178 (5.06%)	15 / 182 (8.24%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ovarian Epithelial Cancer Metastatic			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer metastatic			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (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 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Phlebitis			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Abortion Spontaneous			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-Cardiac Chest Pain			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden unexplained death in epilepsy			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Ovarian Cyst			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Anxiety			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Psychotic Disorder			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	2 / 182 (1.10%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Confusional state			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (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 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine Aminotransferase Increased			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate Aminotransferase Increased			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver Function Test Abnormal			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigation			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Injury, poisoning and procedural complications			
Intentional Overdose			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wrist Fracture			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (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 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (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			
Ataxia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balance Disorder			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral Infarction			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical Root Pain			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Convulsion			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 178 (1.12%)	3 / 182 (1.65%)	
occurrences causally related to treatment / all	1 / 2	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug Withdrawal Convulsions			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	3 / 182 (1.65%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	

Headache			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Partial Seizures with Secondary Generalisation			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sensory disturbance			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (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 / 178 (0.00%)	0 / 182 (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			
Anaemia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Diplopia			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 178 (1.12%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal Pain Upper			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Food Poisoning			
alternative assessment type: Systematic			

subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis Acute			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoaesthesia oral			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile Duct Stone			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			

Drug rash with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (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 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 178 (0.56%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia viral			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subcutaneous abscess			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (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 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Decreased Appetite			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophagia			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 178 (0.00%)	1 / 182 (0.55%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

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%)
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%)	0 / 32 (0.00%)	3 / 203 (1.48%)
occurrences (all)	0	0	3
Mouth injury			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	3 / 203 (1.48%)
occurrences (all)	0	1	3
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			
Dizziness			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 4 (50.00%)	13 / 32 (40.63%)	29 / 203 (14.29%)
occurrences (all)	2	17	46
Headache			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 4 (0.00%)	9 / 32 (28.13%)	31 / 203 (15.27%)
occurrences (all)	0	11	71
Somnolence			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 4 (0.00%)	6 / 32 (18.75%)	20 / 203 (9.85%)
occurrences (all)	0	6	23
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%)	1 / 32 (3.13%)	8 / 203 (3.94%)
occurrences (all)	0	0	10
Epilepsy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences (all)	0	0	4
Partial seizures with secondary generalisation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	0 / 203 (0.00%)
occurrences (all)	0	0	0
Sensory disturbance			

subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 4 (25.00%)	3 / 32 (9.38%)	12 / 203 (5.91%)
occurrences (all)	2	3	13
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%)	0 / 32 (0.00%)	3 / 203 (1.48%)
occurrences (all)	0	0	4
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
Eye disorders			
Diplopia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 4 (25.00%)	2 / 32 (6.25%)	4 / 203 (1.97%)
occurrences (all)	2	0	7
Gastrointestinal disorders			
Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 4 (0.00%)	3 / 32 (9.38%)	11 / 203 (5.42%)
occurrences (all)	0	5	22
Nausea			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 4 (0.00%)	2 / 32 (6.25%)	19 / 203 (9.36%)
occurrences (all)	0	4	35
Colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences (all)	0	0	1
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
Eosinophilia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 32 (0.00%)	1 / 203 (0.49%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
alternative assessment type: Systematic			

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
Nail avulsion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	0 / 203 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Nasopharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	0 / 4 (0.00%)	1 / 32 (3.13%)	13 / 203 (6.40%)
occurrences (all)	0	1	16
Metabolism and nutrition disorders			
Decreased Appetite			
alternative assessment type: Systematic			
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 (>) 1000-1200 milligram (mg)	Carisbamate greater than (>) 800-1000 milligram (mg)	Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	63 / 112 (56.25%)	35 / 51 (68.63%)	73 / 184 (39.67%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 112 (0.89%)	2 / 51 (3.92%)	0 / 184 (0.00%)
occurrences (all)	1	2	0
Tandem gait test abnormal			

subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 112 (0.00%)	2 / 51 (3.92%)	0 / 184 (0.00%)
occurrences (all)	0	2	0
Injury, poisoning and procedural complications			
Face injury			
subjects affected / exposed	0 / 112 (0.00%)	1 / 51 (1.96%)	0 / 184 (0.00%)
occurrences (all)	0	1	0
Medication error			
subjects affected / exposed	3 / 112 (2.68%)	1 / 51 (1.96%)	0 / 184 (0.00%)
occurrences (all)	4	3	0
Joint sprain			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	1	0	0
Mouth injury			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	1	0	0
Open wound			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	1 / 112 (0.89%)	2 / 51 (3.92%)	0 / 184 (0.00%)
occurrences (all)	1	2	0
Rib fracture			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
alternative assessment type: Systematic			
subjects affected / exposed	25 / 112 (22.32%)	22 / 51 (43.14%)	17 / 184 (9.24%)
occurrences (all)	32	32	25

Headache			
alternative assessment type: Systematic			
subjects affected / exposed	16 / 112 (14.29%)	8 / 51 (15.69%)	31 / 184 (16.85%)
occurrences (all)	50	23	58
Somnolence			
alternative assessment type: Systematic			
subjects affected / exposed	7 / 112 (6.25%)	4 / 51 (7.84%)	19 / 184 (10.33%)
occurrences (all)	7	4	20
Amnesia			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Ataxia			
subjects affected / exposed	4 / 112 (3.57%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	4	0	0
Convulsion			
subjects affected / exposed	0 / 112 (0.00%)	1 / 51 (1.96%)	0 / 184 (0.00%)
occurrences (all)	0	1	0
Epilepsy			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	1	0	0
Partial seizures with secondary generalisation			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	1	0	0
Sensory disturbance			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed	5 / 112 (4.46%)	5 / 51 (9.80%)	17 / 184 (9.24%)
occurrences (all)	6	5	18
Asthenia			
subjects affected / exposed	1 / 112 (0.89%)	2 / 51 (3.92%)	0 / 184 (0.00%)
occurrences (all)	1	2	0
Chest pain			

subjects affected / exposed	1 / 112 (0.89%)	2 / 51 (3.92%)	0 / 184 (0.00%)
occurrences (all)	1	3	0
Chills			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	1	0	0
Chest discomfort			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	1 / 112 (0.89%)	1 / 51 (1.96%)	0 / 184 (0.00%)
occurrences (all)	1	1	0
Influenza like illness			
subjects affected / exposed	2 / 112 (1.79%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	2	0	0
Pain			
subjects affected / exposed	2 / 112 (1.79%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	3	0	0
Malaise			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	1	0	0
Pyrexia			
subjects affected / exposed	5 / 112 (4.46%)	2 / 51 (3.92%)	0 / 184 (0.00%)
occurrences (all)	7	2	0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Diplopia			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 112 (8.04%)	4 / 51 (7.84%)	3 / 184 (1.63%)
occurrences (all)	20	7	4
Gastrointestinal disorders			

Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 112 (5.36%)	3 / 51 (5.88%)	4 / 184 (2.17%)
occurrences (all)	6	3	4
Nausea			
alternative assessment type: Systematic			
subjects affected / exposed	8 / 112 (7.14%)	2 / 51 (3.92%)	15 / 184 (8.15%)
occurrences (all)	8	3	24
Colitis			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 112 (0.89%)	2 / 51 (3.92%)	0 / 184 (0.00%)
occurrences (all)	2	2	0
Rhinorrhoea			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Eosinophilia			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 112 (0.89%)	0 / 51 (0.00%)	3 / 184 (1.63%)
occurrences (all)	1	0	3
Dysphoria			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 112 (0.00%)	1 / 51 (1.96%)	0 / 184 (0.00%)
occurrences (all)	0	1	0
Emotional disorder			
subjects affected / exposed	1 / 112 (0.89%)	1 / 51 (1.96%)	0 / 184 (0.00%)
occurrences (all)	1	1	0
Insomnia			

subjects affected / exposed	7 / 112 (6.25%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	11	0	0
Nail avulsion			
subjects affected / exposed	0 / 112 (0.00%)	0 / 51 (0.00%)	0 / 184 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	11 / 112 (9.82%)	6 / 51 (11.76%)	5 / 184 (2.72%)
occurrences (all)	13	10	5
Metabolism and nutrition disorders			
Decreased Appetite			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 112 (2.68%)	0 / 51 (0.00%)	5 / 184 (2.72%)
occurrences (all)	3	0	5

Non-serious adverse events	Carisbamate [CRS] 800 mg	Carisbamate [CRS] 1200 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	105 / 178 (58.99%)	109 / 182 (59.89%)	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Tandem gait test abnormal			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Face injury			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	

Medication error			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Joint sprain			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Mouth injury			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Open wound			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Skin laceration			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Rib fracture			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Dizziness			
alternative assessment type: Systematic			
subjects affected / exposed	52 / 178 (29.21%)	58 / 182 (31.87%)	
occurrences (all)	82	85	
Headache			
alternative assessment type: Systematic			
subjects affected / exposed	32 / 178 (17.98%)	43 / 182 (23.63%)	
occurrences (all)	64	89	
Somnolence			
alternative assessment type: Systematic			
subjects affected / exposed	22 / 178 (12.36%)	28 / 182 (15.38%)	
occurrences (all)	24	30	
Amnesia			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Ataxia			

subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Convulsion			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Epilepsy			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Partial seizures with secondary generalisation			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Sensory disturbance			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Fatigue			
alternative assessment type: Systematic			
subjects affected / exposed	14 / 178 (7.87%)	18 / 182 (9.89%)	
occurrences (all)	16	18	
Asthenia			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Chest pain			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Chills			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Chest discomfort			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Gait disturbance			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Influenza like illness			

subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Pain			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Irritability			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Diplopia			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 178 (5.06%)	14 / 182 (7.69%)	
occurrences (all)	19	22	
Gastrointestinal disorders			
Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 178 (5.06%)	8 / 182 (4.40%)	
occurrences (all)	10	8	
Nausea			
alternative assessment type: Systematic			
subjects affected / exposed	11 / 178 (6.18%)	23 / 182 (12.64%)	
occurrences (all)	15	25	
Colitis			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Eosinophilia			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Anxiety			
alternative assessment type: Systematic			
subjects affected / exposed	9 / 178 (5.06%)	4 / 182 (2.20%)	
occurrences (all)	11	4	
Dysphoria			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Depression			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Emotional disorder			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Nail avulsion			
subjects affected / exposed	0 / 178 (0.00%)	0 / 182 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Nasopharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	6 / 178 (3.37%)	12 / 182 (6.59%)	
occurrences (all)	8	12	
Metabolism and nutrition disorders			

Decreased Appetite alternative assessment type: Systematic subjects affected / exposed occurrences (all)	9 / 178 (5.06%) 12	5 / 182 (2.75%) 5	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
27 February 2009	Description Added a definition in the 'other important medical event" category to indicate that suspected transmission of an infectious agent by a medicinal product was considered a serious adverse event. The statistical procedures section was modified to indicate that physical and neurologic examination results were to be analyzed by tabulation of abnormal results, not by change from baseline at each time point. The section on the use of concomitant AEDs was updated to clarify the criteria for inadequate response to prior AEDs, and indicate that subjects with a history of 10 or more generalized seizures (of any type) per month must have exhibited inadequate response to at least 3 prior AEDs. Additional clarifications were made to the Prohibitions and Restrictions, and to the Pre-study and Concomitant The Study Protocol was also updated to specify that subject who could tolerate the dosage during the first week of the titration period, or who could not tolerate a dosage reduction during Weeks 2 through 4 as a result of side effects, were to be withdrawn from the study. Finally, the sections on Laboratory Tests, and ECG collection, were clarified to remove serum pregnancy testing (only urine pregnancy tests to be performed). The pregnancy test was added for Visit 3 (Day 1). A second ECG reading was made at visit 3 (baseline). The visit window for Visits X1 to X3 of study was changed from 2 weeks to 3 days. The statistical step-down procedure was modified for both the primary and secondary efficacy endpoints. The step-down procedure was planned to ensure the type I error rate due to multiple treatment comparisons was controlled at the 0.05 level. First, the carisbamate 800-mg/day and 1200 -mg/day dosage groups were be combined as a single group, and the combined carisbamate group compared with the placebo group for the endpoint.
22 September 2009	A change was made to specify that subjects currently receiving double-blind study medication, or who have been receiving carisbamate in the extension phase for less than 6 weeks, must be withdrawn from the study if they experience during the study, or have a history (at any time in their life) of Stevens Johnson Syndrome, toxic epidermal necrolysis, drug reaction with eosinophilia and systemic symptoms, a drug-related exfoliative rash, any drug-related rash requiring hospitalization, or rash associated with an AED that involved conjunctiva or mucosae, or a maculopapular rash that required discontinuation of an antiepileptic drug [AED]. Finally an amendment was made to specify that enrolled subjects who concurrently develop two or more of the following signs and symptoms should be withdrawn from the study, unless these are clearly attributable to another documented illness (e.g.,infectious pneumonia): rash; fever (Less than [>] 38.5ºC); lymphadenopathy (must have either enlargement of nodes relative to baseline, or tenderness); eosinophilia (absolute eosinophil count greater or equal to 700/microliter, or, if elevated at baseline, an increase of more than 50%); alanine aminotransferase [ALT] greater than 2 times the upper limit of normal (ULN), confirmed by a repeat measurement; signs or symptoms of significant pulmonary, cardiac, renal, muscular or pancreatic involvement.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported