Clinical trial results:
Long-Term Eslicarbazepine Acetate Extension Study

Summary

EudraCT number	2010-019000-22
Trial protocol	CZ ES PL BG
Global end of trial date	15 April 2017

Results information

Result version number	v3 (current)
This version publication date	24 August 2018
First version publication date	29 April 2018
Version creation reason	• New data added to full data set updating with new information
Summary attachment (see zip file)	update results to match ct.gov (clinical trials update for EudraCT.pdf)

Trial information

Trial identification

Sponsor protocol code	093-050

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00910247
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Sunovion Pharmaceuticals Inc.
Sponsor organisation address	84 Waterford Drive, Marlboro, United States, 01752
Public contact	CNS Medical Director, Sunovion Pharmaceuticals Inc., 1 866-503-6351, clinicaltrialsdisclosure@sunovion.com
Scientific contact	CNS Medical Direcctor, Sunovion Pharmaceuticals Inc., 1 866-503-6351, clinicaltrialsdisclosure@sunovion.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 April 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 April 2017
Global end of trial reached?	Yes
Global end of trial date	15 April 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the 1-year and post-1-year safety and tolerability of eslicarbazepine acetate flexible dosing within the range of 800 mg to 2400 mg in subjects with partial epilepsy who have participated in an 18-week double-blind eslicarbazepine acetate monotherapy study (Protocols 093-045 or 093-046).

Protection of trial subjects:

This study was conducted according to the protocol, ICH Good Clinical Practice (GCP), ICH guidelines and the ethical principles that have their origin in the Declaration of Helsinki

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 December 2009
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Bulgaria: 18
Country: Number of subjects enrolled	Czech Republic: 27
Country: Number of subjects enrolled	United States: 167
Country: Number of subjects enrolled	Canada: 3
Country: Number of subjects enrolled	Serbia: 2
Country: Number of subjects enrolled	Ukraine: 57
Worldwide total number of subjects	274
EEA total number of subjects	45

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)	12

Adults (18-64 years)	258
From 65 to 84 years	4
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects who participated in either study 093-045 (NCT00866775)or study 093-046 (NCT01091662) were eligible to participate in study 093-050

Pre-assignment

Screening details:

Subjects who completed the 18-week treatment period or exited the study per protocol may be eligible to participate. Subjects who discontinued for reasons other than reaching the exit criteria may be eligible if there is no safety concern, however, subjects must have completed at least the first 3 weeks of the 18-week doubleblind treatment

Period 1

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

Arms

Arm title	eslicarbazepine acetate

Arm description:

Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Arm type	Experimental
Investigational medicinal product name	eslicarbazepine acetate
Investigational medicinal product code	
Other name	DRP-0002093, BIA 2-093
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

800 to 2400 mg once daily (QD)

Number of subjects in period 1	eslicarbazepine acetate
Started	274
Completed	205
Not completed	69
Adverse event, serious fatal	2
Physician decision	3
Consent withdrawn by subject	25
Adverse event, non-fatal	15
Not Collected	4
Lost to follow-up	10
Protocol deviation	10

Baseline characteristics

Reporting groups	
Reporting group title	Overall Study
Reporting group description:	
Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)	

Reporting group values	Overall Study	Total	
Number of subjects	274	274	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	12	12	
Adults (18-64 years)	258	258	
From 65-84 years	4	4	
85 years and over	0	0	
Age continuous Units: years			
arithmetic mean	37.9		
standard deviation	± 12.70	-	
Gender categorical Units: Subjects			
Female	134	134	
Male	140	140	

End points

End points reporting groups

Reporting group title	eslicarbazepine acetate

Reporting group description:

Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD
eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Primary: Number and percent of subjects with treatment emergent adverse events

End point title	Number and percent of subjects with treatment emergent adverse events[1]

End point description:

Number and percent of subjects with treatment emergent adverse events

End point type	Primary

End point timeframe:

One year

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: no statistical analysis is required for this endpoint

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	274			
Units: subjects	220			

Statistical analyses

No statistical analyses for this end point

Secondary: Number and percentage of subjects with potentially clinically significant clinical laboratory evaluations

End point title	Number and percentage of subjects with potentially clinically significant clinical laboratory evaluations

End point description:

End point type	Secondary

End point timeframe:

One Year

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	274			
Units: subjects	186			

Statistical analyses

No statistical analyses for this end point

Secondary: Number and percent of subjects with normal baseline sodium reaching blood sodium ≤135 mmol/L, ≤130 mmol/L, and ≤125 mmol/L

End point title	Number and percent of subjects with normal baseline sodium reaching blood sodium ≤135 mmol/L, ≤130 mmol/L, and ≤125 mmol/L

End point description:

Number and percentage of subjects who had normal sodium value (i.e. >135 mEq/L) at baseline but reached <=135 mEq/L and >130 mEq/L, <=130 mEq/L and >125 mEq/L, or <=125 mEq/L at any post baseline.

End point type	Secondary

End point timeframe:

One year

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	261			
Units: subjects				
≤135 mmol/L	48			
≤130 mmol/L	22			
≤125 mmol/L	4			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion (%) of subjects with increase of body weight ≥7%

End point title	Proportion (%) of subjects with increase of body weight ≥7%

End point description:

End point type	Secondary

End point timeframe:

One year

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	274			
Units: percentage of participants	27			

Statistical analyses

No statistical analyses for this end point

Secondary: Number and percentage of subjects with orthostatic effects

End point title	Number and percentage of subjects with orthostatic effects

End point description:

End point type	Secondary

End point timeframe:

One year

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	274			
Units: subjects	67			

Statistical analyses

No statistical analyses for this end point

Secondary: Number and percentage of subjects with QTc-F changes (in categories) from baseline.

End point title	Number and percentage of subjects with QTc-F changes (in categories) from baseline.

End point description:

Based on the numbers of subjects who had at least one post-baseline assessment, the number and percentage of subjects with QTcF values in the following categories were summarized:
1. >500 millisecond (msec) at any post-baseline timepoint but not present at baseline
2. >480 msec at any post-baseline timepoint but not present at baseline
3.>450 msec at any post-baseline timepoint but not present at baseline
4. Change from Baseline >=60 ms for at least one post-baseline measurement
5. Change from Baseline >=30 ms for at least one post-baseline measurement and <60 ms for all post-baseline measurement

End point type	Secondary

End point timeframe:

baseline, month 12

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	272			
Units: subjects				
>500ms at any postbaseline not present at baseline	0			
>450ms at any postbaseline not present at baseline	9			
>480ms at any postbaseline not present at baseline	1			
CFB >=60 ms for at least one post-baseline	0			
CFB>=30ms for at least one &<60ms for all PBL	42			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion (%) of events in each classification of the Columbia Suicide Severity Rating Scale (C SSRS)

End point title	Proportion (%) of events in each classification of the Columbia Suicide Severity Rating Scale (C SSRS)

End point description:

The C-SSRS is an instrument designed to systematically assess and track suicidal behavior and suicidal ideation. The C-SSRS will be completed by the Investigator or Sub-Investigator (or qualified site personnel).

Suicidal ideation is collected as any occurrence of wish to be dead, non-specific active suicidal thoughts, active suicidal ideation with any methods (not plan) without intent to act, active suicidal ideation with some intent to act, without specific plan, active suicidal ideation with specific plan and intent.

Suicidal behavior is collected as any occurrence of actual attempts, Non-Suicidal Self-Injurious Behavior, interrupted attempts, aborted attempts, or preparatory acts or behavior, suicidal behavior.

Any suicidality is defined as having at least one occurrence of Suicidal Behavior or Suicidal Ideation.

End point type	Secondary

End point timeframe:

One year

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	274			
Units: percentage of events				
Any Suicidality	4			
Any suicidal behavior	0			
any suicidal ideation	3			

Statistical analyses

No statistical analyses for this end point

Secondary: Responder rate (proportion [%] of subjects with a ≥50% reduction of seizure frequency from baseline)

End point title	Responder rate (proportion [%] of subjects with a ≥50% reduction of seizure frequency from baseline)

End point description:

End point type	Secondary

End point timeframe:

One year

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	274			
Units: percentage of participants	62			

Statistical analyses

No statistical analyses for this end point

Secondary: Proportion (%) of subjects that are seizure-free during study

End point title	Proportion (%) of subjects that are seizure-free during study

End point description:

End point type	Secondary

End point timeframe:

One year

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	274			
Units: percentage of participants	7			

Statistical analyses

No statistical analyses for this end point

Secondary: Completion rate (% of subjects completing the one year treatment)

End point title	Completion rate (% of subjects completing the one year treatment)

End point description:

End point type	Secondary

End point timeframe:

One Year

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	274			
Units: percentage of participants	74			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in total score from baseline in 31-Item Quality of Life in Epilepsy (QOLIE-31)

End point title	Change in total score from baseline in 31-Item Quality of Life in Epilepsy (QOLIE-31)

End point description:

Change in the overall score from baseline in 31-Item Quality of Life in Epilepsy (QOLIE-31)

The QOLIE-31 overall score was obtained by using a weighted average of multi-item scale scores. The recorded responses were converted to 0-100 point scales. The mean of the individual item scores in each subgroup were calculated, with higher converted scores reflecting better quality of life.

End point type	Secondary

End point timeframe:

baseline and month 12

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	274			
Units: change in score				
arithmetic mean (standard deviation)	6.6 (± 15.29)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in total score from baseline in Montgomery-Asberg Depression Rating Scale (MADRS)

End point title	Change in total score from baseline in Montgomery-Asberg Depression Rating Scale (MADRS)

End point description:

The total score of MADRS is defined as the sum of all individual item scores. Each of the 10 symptoms of depression on MADRS is measured on a scale of 0 to 6 with 0 representing the lowest severity of the symptom and 6 representing the highest severity.

End point type	Secondary

End point timeframe:

One year

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	274			
Units: change in score				
arithmetic mean (standard deviation)	-1.5 (± 6.17)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in total score from baseline in MADRS in those subjects with a MADRS score of ≥14 at screening

End point title	Change in total score from baseline in MADRS in those subjects with a MADRS score of ≥14 at screening

End point description:

The total score of MADRS is defined as the sum of all individual item scores . Each of the 10 symptoms of depression on MADRS is measured on a scale of 0 to 6 with 0 representing the lowest severity of the symptom and 6 representing the highest severity.

End point type	Secondary

End point timeframe:

baseline and month 12

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	274			
Units: change in score				
arithmetic mean (standard deviation)	-9.4 (± 5.69)			

Statistical analyses

No statistical analyses for this end point

Secondary: Completion rate (% of subjects completing each visit post-one year)

End point title	Completion rate (% of subjects completing each visit post-one year)

End point description:

End point type	Secondary

End point timeframe:

One year

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	198			
Units: percentage of participants	67			

Statistical analyses

No statistical analyses for this end point

Secondary: Time on esclicarbazepine acetate monotherapy

End point title	Time on esclicarbazepine acetate monotherapy

End point description:

The start of the monotherapy period was defined as the date of termination of all other anti-epileptic drugs while taking study medication. Time on eslicarbazepine acetate monotherapy is defined from the date of the first monotherapy dose in 093-045 or 093-046 study to the last known dose of monotherapy treatment, regardless of dose change and the time gap between the parent studies and the current study.

End point type	Secondary

End point timeframe:

One year

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	238			
Units: days				
median (confidence interval 95%)	0 (0 to 0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change in seizure frequency from baseline

End point title	Change in seizure frequency from baseline

End point description:

Relative (%) change in standard seizure frequency(SSF) from baseline

End point type	Secondary

End point timeframe:

month 12 from baseline

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	274			
Units: percent change				
median (inter-quartile range (Q1-Q3))	-66.4 (-88.8 to -32.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Treatment retention time (time to withdrawal due to lack of efficacy or adverse events)

End point title	Treatment retention time (time to withdrawal due to lack of efficacy or adverse events)

End point description:

The retention time is defined from the start of eslicarbazepine acetate monotherapy period in 093-045 or 093-046 to the last known dose of open-label eslicarbazepine acetate. The time may include taking eslicarbazepine acetate concomitantly with other anti-epileptic drugs. If a subject’s termination reason(s) includes: withdrawal of consent, lost to follow-up, physician decision or other, then it was assumed the subject terminated the study due to lack of efficacy.

End point type	Secondary

End point timeframe:
One year

End point values	eslicarbazepine acetate			
Subject group type	Reporting group			
Number of subjects analysed	255			
Units: days				
median (confidence interval 95%)	0 (0 to 0)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
One year	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	13.1

Reporting groups	
Reporting group title	eslicarbazepine acetate

Reporting group description:

Open-label treatment with eslicarbazepine acetate will be at doses between 800 and 2400 mg QD
Eslicarbazepine acetate: 800 to 2400 mg once daily (QD)

Serious adverse events	eslicarbazepine acetate		
Total subjects affected by serious adverse events			
subjects affected / exposed	32 / 274 (11.68%)		
number of deaths (all causes)	2		
number of deaths resulting from adverse events	2		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
fallopian tube cancer			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
non-small cel lung cancer metastatic			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
ovarian cancer			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
accelerated hypertensionaccelerated hypertension			

subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
irritability			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
non-cardiac chest pain			
subjects affected / exposed	3 / 274 (1.09%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 0		
sudden unexplained death in epilepsy			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Respiratory, thoracic and mediastinal disorders			
emphysema			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
depression			
subjects affected / exposed	2 / 274 (0.73%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
suicidal ideation			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
electroencephalogram			

subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
accidental overdose			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
collapse of lung			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
fall			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
post concussion syndrome			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Therapeutic agent toxicity			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
sinus tachycardia			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
akathisia			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		

complex partial seizures				
subjects affected / exposed	3 / 274 (1.09%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
grand mal convulsion				
subjects affected / exposed	1 / 274 (0.36%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
partial seizures with secondary generalisation				
subjects affected / exposed	7 / 274 (2.55%)			
occurrences causally related to treatment / all	3 / 7			
deaths causally related to treatment / all	0 / 0			
postictal paralysis				
subjects affected / exposed	1 / 274 (0.36%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
simple partial seizures				
subjects affected / exposed	2 / 274 (0.73%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	0 / 0			
status epilepticus				
subjects affected / exposed	1 / 274 (0.36%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ear and labyrinth disorders				
vertigo				
subjects affected / exposed	1 / 274 (0.36%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
abdominal pain upper				
subjects affected / exposed	1 / 274 (0.36%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

colitis				
subjects affected / exposed	1 / 274 (0.36%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
pancreatitis				
subjects affected / exposed	1 / 274 (0.36%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
vomiting				
subjects affected / exposed	1 / 274 (0.36%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
cholelithiasis obstructive				
subjects affected / exposed	1 / 274 (0.36%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
histoplasmosis				
subjects affected / exposed	1 / 274 (0.36%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
pneumonia				
subjects affected / exposed	1 / 274 (0.36%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
tooth infection				
subjects affected / exposed	1 / 274 (0.36%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
nephrolithiasis				
subjects affected / exposed	1 / 274 (0.36%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Musculoskeletal and connective tissue disorders			
arthritis			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
muscle twitching			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Osteoarthritis			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
chronic sinusitis			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
failure to thrive			
subjects affected / exposed	1 / 274 (0.36%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	eslicarbazepine acetate		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	167 / 274 (60.95%)		
Injury, poisoning and procedural complications			
fall			
subjects affected / exposed	20 / 274 (7.30%)		
occurrences (all)	33		
Nervous system disorders			

complex partial seizures subjects affected / exposed occurrences (all)	14 / 274 (5.11%) 18		
dizziness subjects affected / exposed occurrences (all)	46 / 274 (16.79%) 81		
headache subjects affected / exposed occurrences (all)	64 / 274 (23.36%) 114		
General disorders and administration site conditions fatigue subjects affected / exposed occurrences (all)	23 / 274 (8.39%) 25		
Gastrointestinal disorders diarrhoea subjects affected / exposed occurrences (all)	15 / 274 (5.47%) 19		
nausea subjects affected / exposed occurrences (all)	24 / 274 (8.76%) 31		
vomiting subjects affected / exposed occurrences (all)	16 / 274 (5.84%) 20		
Psychiatric disorders depression subjects affected / exposed occurrences (all)	18 / 274 (6.57%) 19		
insomnia subjects affected / exposed occurrences (all)	15 / 274 (5.47%) 18		
Musculoskeletal and connective tissue disorders back pain subjects affected / exposed occurrences (all)	16 / 274 (5.84%) 16		
Infections and infestations			

influenza subjects affected / exposed occurrences (all)	14 / 274 (5.11%) 15		
nasopharyngitis subjects affected / exposed occurrences (all)	24 / 274 (8.76%) 35		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported