Clinical trial results:
A PLACEBO-CONTROLLED, ESCALATING DOSE, MULTIPLE DOSE STUDY TO EVALUATE THE SAFETY, TOLERABILITY AND PHARMACOKINETICS OF PREGABALIN IN PEDIATRIC PATIENTS WITH PARTIAL ONSET SEIZURES

Summary

EudraCT number	2010-020730-26
Trial protocol	FR
Global end of trial date	13 November 2012

Results information

Result version number	v1 (current)
This version publication date	30 May 2016
First version publication date	30 July 2015

Trial information

Trial identification

Sponsor protocol code	A0081074

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT00437281
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pfizer Inc.
Sponsor organisation address	235 East 42nd Street,, New York, United States, NY 10017
Public contact	Pfizer ClinicalTrials.gov Call Center , Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.com
Scientific contact	Pfizer ClinicalTrials.gov Call Center , Pfizer Inc., 001 8007181021, ClinicalTrials.gov_Inquiries@pfizer.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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	11 April 2013
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	13 November 2012
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the escalating single- and multiple-dose safety and tolerability of pregabalin, in comparison to placebo, in pediatric subjects 1 month through 16 years of age with partial onset seizures.
To evaluate the single-dose and steady-state pharmacokinetics of pregabalin in pediatric subjects 1 month through 16 years of age with partial onset seizures.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	30 April 2007
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	Korea, Republic of: 3
Country: Number of subjects enrolled	United States: 58
Country: Number of subjects enrolled	Mexico: 4
Worldwide total number of subjects	65
EEA total number of subjects	0

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)	16
Children (2-11 years)	34

Adolescents (12-17 years)	15
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Subjects who completed this study and who tolerated study medication were eligible to enroll in study A0081075 (NCT00448916), a 12-month open-label extension study of pregabalin.

Period 1

Period 1 title	Overall trial (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Investigator, Carer, Assessor, Subject

Arms

Are arms mutually exclusive?	Yes
Arm title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)

Arm description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD 0144723
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation 2.5 milligram per kilogram per day (mg/kg/day) in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 1.25 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)

Arm description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administerd on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD 0144723
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation 5 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 2.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)

Arm description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD 0144723
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation 10 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)

Arm description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD 0144723
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation 15 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 7.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Placebo (Age Cohort: 1 to 23 Months)

Arm description:

Subjects of 1 to 23 months of age received placebo matched to pregabalin oral liquid formulation 2 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation of different doses were administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 1 to 23 months of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 1.25 mg/kg, 2.5 mg/kg, 5 mg/kg or 7.5mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)

Arm description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental

Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD-144723
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation 2.5 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 1.25 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)

Arm description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD-144723
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation 5 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 2.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)

Arm description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD-144723
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation 10 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)

Arm description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD-144723
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation 15 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 7.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Placebo (Age Cohort: 2 to 6 Years)

Arm description:

Subjects of 2 to 6 years of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation of different doses were administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 2 to 6 years of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 1.25 mg/kg, 2.5 mg/kg, 5 mg/kg or 7.5mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)

Arm description:

Subjects of 7 to 11 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD-144723
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 7 to 11 years of age received pregabalin oral liquid formulation 2.5 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 1.25 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)

Arm description:

Subjects of 7 to 11 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD-144723
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 7 to 11 years of age received pregabalin oral liquid formulation 5 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 2.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-

label extension study were tapered off medication over 1 week.

Arm title	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)

Arm description:

Subjects of 7 to 11 years of age received pregabalin oral capsule in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD 0144723
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects of 7 to 11 years of age received pregabalin oral capsule 10 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule 5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)

Arm description:

Subjects of 7 to 11 years of age received pregabalin oral capsule in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD-144723
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects of 7 to 11 years of age received pregabalin oral capsule 15 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule 7.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Placebo (Age Cohort: 7 to 11 Years)

Arm description:

Subjects of 7 to 11 years of age received placebo matched to pregabalin oral liquid formulation or capsule 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation or pregabalin oral capsule of different doses were administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 7 to 11 years of age received placebo matched to pregabalin oral liquid formulation or capsule 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of

pregabalin oral liquid formulation 1.25 mg/kg or 2.5 mg/kg, or pregabalin oral capsule 5 mg/kg or 7.5mg/kg on Day 8.Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)

Arm description:

Subjects of 12 to 16 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD 0144723
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 12 to 16 years of age received pregabalin oral liquid formulation 2.5 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 1.25 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)

Arm description:

Subjects of 12 to 16 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD 0144723
Other name	
Pharmaceutical forms	Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 12 to 16 years of age received pregabalin oral liquid formulation 5 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 2.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)

Arm description:

Subjects of 12 to 16 years of age received pregabalin oral capsule in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD 0144723
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects of 12 to 16 years of age received pregabalin oral capsule 10 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule 5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label

extension study were tapered off medication over 1 week.

Arm title	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)

Arm description:

Subjects of 12 to 16 years of age received pregabalin oral capsule in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Experimental
Investigational medicinal product name	Pregabalin
Investigational medicinal product code	PD 0144723
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects of 12 to 16 years of age received pregabalin oral capsule 15 mg/kg/day in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule 7.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm title	Placebo (Age Cohort: 12 to 16 Years)

Arm description:

Subjects of 12 to 16 years of age received placebo matched to pregabalin oral liquid formulation or capsule 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation or pregabalin oral capsule of different doses were administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule, Oral liquid
Routes of administration	Oral use

Dosage and administration details:

Subjects of 12 to 16 years of age received placebo matched to pregabalin oral liquid formulation or capsule 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 1.25 mg/kg or 2.5 mg/kg, or pregabalin oral capsule 5 mg/kg or 7.5mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Number of subjects in period 1	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)
Started	3	3	3
Completed	3	3	3
Not completed	0	0	0
Adverse event, non-fatal	-	-	-

Lost to follow-up	-	-	-

Number of subjects in period 1	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)	Placebo (Age Cohort: 1 to 23 Months)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)
Started	3	4	4
Completed	2	4	3
Not completed	1	0	1
Adverse event, non-fatal	1	-	1
Lost to follow-up	-	-	-

Number of subjects in period 1	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)
Started	3	3	3
Completed	3	3	3
Not completed	0	0	0
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Placebo (Age Cohort: 2 to 6 Years)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)
Started	5	3	3
Completed	4	3	3
Not completed	1	0	0
Adverse event, non-fatal	1	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)	Placebo (Age Cohort: 7 to 11 Years)
Started	2	3	5
Completed	2	2	4
Not completed	0	1	1
Adverse event, non-fatal	-	1	1
Lost to follow-up	-	-	-

Number of subjects in period 1	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)
Started	3	3	4
Completed	3	3	4
Not completed	0	0	0
Adverse event, non-fatal	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)	Placebo (Age Cohort: 12 to 16 Years)
Started	2	3
Completed	1	2
Not completed	1	1
Adverse event, non-fatal	1	-
Lost to follow-up	-	1

Reporting groups

Reporting group title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administerd on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Placebo (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received placebo matched to pregabalin oral liquid formulation 2 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation of different doses were administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Placebo (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation of different doses were administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received pregabalin oral capsule in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received pregabalin oral capsule in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Placebo (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received placebo matched to pregabalin oral liquid formulation or capsule 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation or pregabalin oral capsule of different doses were administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received pregabalin oral capsule in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received pregabalin oral capsule in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Placebo (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received placebo matched to pregabalin oral liquid formulation or capsule 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation or pregabalin oral capsule of different doses were administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)
Number of subjects	3	3	3
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	1.2	1.4	0.7
standard deviation	± 0.7	± 0.5	± 0.5
Gender categorical Units: Subjects			
Female	1	2	1
Male	2	1	2

Reporting group values	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)	Placebo (Age Cohort: 1 to 23 Months)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)
Number of subjects	3	4	4
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	0.6	1.6	4
standard deviation	± 0.1	± 0.3	± 0.8
Gender categorical Units: Subjects			
Female	2	2	4
Male	1	2	0

Reporting group values	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)
Number of subjects	3	3	3
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	2.9	4	3.9
standard deviation	± 0.1	± 1.7	± 1.8

Gender categorical Units: Subjects			
Female	2	1	1
Male	1	2	2

Reporting group values	Placebo (Age Cohort: 2 to 6 Years)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)
Number of subjects	5	3	3
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	3.7	9.3	9.7
standard deviation	± 1	± 1.2	± 2.3
Gender categorical Units: Subjects			
Female	3	2	1
Male	2	1	2

Reporting group values	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)	Placebo (Age Cohort: 7 to 11 Years)
Number of subjects	2	3	5
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	10	9	9.2
standard deviation	± 0	± 1	± 1.5
Gender categorical Units: Subjects			
Female	0	0	4
Male	2	3	1

Reporting group values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)
Number of subjects	3	3	4
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	15.7	13.7	14
standard deviation	± 0.6	± 2.1	± 1.8
Gender categorical Units: Subjects			
Female	2	1	0

Male	1	2	4

Reporting group values	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)	Placebo (Age Cohort: 12 to 16 Years)	Total
Number of subjects	2	3	65
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	15.5	13	
standard deviation	± 0.7	± 1.7	-
Gender categorical Units: Subjects			
Female	0	3	32
Male	2	0	33

End points

End points reporting groups

Reporting group title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administerd on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Placebo (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received placebo matched to pregabalin oral liquid formulation 2 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation of different doses were administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Placebo (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation of different doses were administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received pregabalin oral capsule in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received pregabalin oral capsule in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Placebo (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received placebo matched to pregabalin oral liquid formulation or capsule 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation or pregabalin oral capsule of different doses were administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received pregabalin oral liquid formulation in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received pregabalin oral capsule in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received pregabalin oral capsule in 2 equally divided doses 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Placebo (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received placebo matched to pregabalin oral liquid formulation or capsule 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation or pregabalin oral capsule of different doses were administered on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 1 to 23 Months)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 1 to 23 months of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 1.25 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 1 to 23 Months)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 1 to 23 months of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 2.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 5 mg/kg (Age Cohort: 1 to 23 Months)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 1 to 23 months of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 1 to 23 Months)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 1 to 23 months of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 7.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 2 to 6 Years)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 2 to 6 years of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 1.25 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 2 to 6 Years)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 2 to 6 years of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 2.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 5 mg/kg (Age Cohort: 2 to 6 Years)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 2 to 6 years of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 2 to 6 Years)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 2 to 6 years of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 7.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 7 to 11 Years)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 7 to 11 years of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 1.25 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 7 to 11 Years)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 7 to 11 years of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 2.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 5 mg/kg (Age Cohort: 7 to 11 Years)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 7 to 11 years of age received placebo matched to pregabalin oral capsule 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule 5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 7 to 11 Years)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 7 to 11 years of age received placebo matched to pregabalin oral capsule 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule 7.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 12 to 16 Years)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 12 to 16 years of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 1.25 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 12 to 16 Years)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 12 to 16 years of age received placebo matched to pregabalin oral liquid formulation 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation 2.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension

study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 5 mg/kg (Age Cohort: 12 to 16 Years)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 12 to 16 years of age received placebo matched to pregabalin oral capsule 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule 5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Subject analysis set title	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 12 to 16 Years)
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects of 12 to 16 years of age received placebo matched to pregabalin oral capsule 12 hours apart for 7 days as double-blind treatment. Single open-label morning dose of pregabalin oral capsule 7.5 mg/kg on Day 8. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Primary: Number of Treatment-Emergent Adverse Events (AEs) by Severity: Double-blind Treatment

End point title	Number of Treatment-Emergent Adverse Events (AEs) by Severity: Double-blind Treatment[1]

End point description:

Analysis for severity of AEs was performed separately for double-blind and open-label treatment. AE = any untoward medical occurrence in subject who received study drug without regard to possibility of causal relationship. AEs were classified as mild, moderate and severe based on severity assessment: Mild = no interference with subject's usual function; Moderate = some interference with subject's usual function; Severe = significant interference with subject's usual function. Treatment-emergent events for double-blind treatment included events between baseline and Day 7 that were absent before treatment or that worsened relative to pretreatment state. Subjects may experience more than 1 AE. Safety analysis set included all subjects who received at least 1 dose of study medication.

End point type	Primary

End point timeframe:

Baseline to Day 7

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: Only descriptive data was planned to be reported for this endpoint.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: adverse events				
Mild	0	2	2	4
Moderate	1	1	0	1
Severe	0	0	0	1

End point values	Placebo (Age Cohort: 1 to 23 Months)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	3	3
Units: adverse events				
Mild	1	1	4	5
Moderate	1	2	0	0
Severe	0	0	0	0

End point values	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)	Placebo (Age Cohort: 2 to 6 Years)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5	3	3
Units: adverse events				
Mild	5	13	0	3
Moderate	0	3	2	0
Severe	0	0	0	0

End point values	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)	Placebo (Age Cohort: 7 to 11 Years)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	5	3
Units: adverse events				
Mild	3	5	2	0
Moderate	0	2	0	1
Severe	0	3	0	0

End point values	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)	Placebo (Age Cohort: 12 to 16 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	2	3
Units: adverse events				
Mild	2	11	2	0
Moderate	1	4	3	0
Severe	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Treatment-Emergent Adverse Events (AEs) by Severity: Open-label Treatment

End point title	Number of Treatment-Emergent Adverse Events (AEs) by Severity: Open-label Treatment[2]

End point description:

Analysis for severity of AEs was performed separately for double-blind and open-label treatment. AE = any untoward medical occurrence in subject who received study drug without regard to possibility of causal relationship. AEs were classified as mild, moderate and severe based on severity assessment: Mild = no interference with subject's usual function; Moderate = some interference with subject's usual function; Severe = significant interference with subject's usual function. Treatment-emergent events for open-label treatment included events between Day 8 and 28 days after the open-label dose that were absent before treatment or that worsened relative to pretreatment state. Subjects may experience more than 1 AE. Safety analysis set included all subjects who received at least 1 dose of study medication.

End point type	Primary

End point timeframe:

Day 8 up to 28 days after open-label dose of study medication

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: adverse events				
Mild	0	0	0	1
Moderate	0	0	0	0
Severe	0	0	0	0

End point values	Placebo (Age Cohort: 1 to 23 Months)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	3	3
Units: adverse events				
Mild	2	0	0	0
Moderate	1	0	0	0
Severe	0	0	0	0

End point values	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)	Placebo (Age Cohort: 2 to 6 Years)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5	3	3
Units: adverse events				
Mild	0	1	0	0
Moderate	1	1	0	0

Severe	0	0	0	0

End point values	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)	Placebo (Age Cohort: 7 to 11 Years)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	5	3
Units: adverse events				
Mild	1	0	0	0
Moderate	0	0	1	0
Severe	0	0	1	0

End point values	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)	Placebo (Age Cohort: 12 to 16 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	2	3
Units: adverse events				
Mild	0	0	0	0
Moderate	1	0	0	0
Severe	1	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Significant Change in Physical and Neurological Findings

End point title	Number of Subjects With Clinically Significant Change in Physical and Neurological Findings

End point description:

Full physical examination included examination of the abdomen, breasts, lungs, lymph nodes, mouth, genitourinary, musculoskeletal and neurological systems, skin, extremities, head, heart, ears, eyes, neck, nose, ocular fundi, throat and thyroid gland. The neurological exam was performed by a pediatric neurologist or qualified investigator. Safety analysis set included all subjects who received at least 1 dose of study medication.

End point type	Secondary

End point timeframe:

Baseline up to 7 days post-last dose of study medication

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: subjects	0	0	0	0

End point values	Placebo (Age Cohort: 1 to 23 Months)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	3	3
Units: subjects	0	1	0	0

End point values	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)	Placebo (Age Cohort: 2 to 6 Years)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	5	3	3
Units: subjects	0	1	0	0

End point values	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)	Placebo (Age Cohort: 7 to 11 Years)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	3	5	3
Units: subjects	1	1	0	0

End point values	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)	Placebo (Age Cohort: 12 to 16 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	2	3
Units: subjects	0	1	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: 28-Day Seizure Frequency Rate

End point title	28-Day Seizure Frequency Rate

End point description:

Seizure frequency was reported by subject's parent or guardian from randomization to 7 days post-last dose of study medication. 28-day seizure frequency rate = (number of seizures in observation period/number of days in observation period) multiplied by (*) 28. Results are not reported since the data was reported in individual subject listings but not summarized for analysis.

End point type	Secondary

End point timeframe:

Baseline up to 7 days post-last dose of study medication

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[3]	0[4]	0[5]	0[6]
Units: seizure				
number (not applicable)				

Notes:

[3] - Results not reported since the data was reported in individual subject listings but not summarized.

[4] - Results not reported since the data was reported in individual subject listings but not summarized.

[5] - Results not reported since the data was reported in individual subject listings but not summarized.

[6] - Results not reported since the data was reported in individual subject listings but not summarized.

End point values	Placebo (Age Cohort: 1 to 23 Months)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[7]	0[8]	0[9]	0[10]
Units: seizure				
number (not applicable)				

Notes:

[7] - Results not reported since the data was reported in individual subject listings but not summarized.

[8] - Results not reported since the data was reported in individual subject listings but not summarized.

[9] - Results not reported since the data was reported in individual subject listings but not summarized.

[10] - Results not reported since the data was reported in individual subject listings but not summarized.

End point values	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)	Placebo (Age Cohort: 2 to 6 Years)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[11]	0[12]	0[13]	0[14]
Units: seizure				
number (not applicable)				

Notes:

[11] - Results not reported since the data was reported in individual subject listings but not summarized.
[12] - Results not reported since the data was reported in individual subject listings but not summarized.
[13] - Results not reported since the data was reported in individual subject listings but not summarized.
[14] - Results not reported since the data was reported in individual subject listings but not summarized.

End point values	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)	Placebo (Age Cohort: 7 to 11 Years)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[15]	0[16]	0[17]	0[18]
Units: seizure				
number (not applicable)				

Notes:

[15] - Results not reported since the data was reported in individual subject listings but not summarized.
[16] - Results not reported since the data was reported in individual subject listings but not summarized.
[17] - Results not reported since the data was reported in individual subject listings but not summarized.
[18] - Results not reported since the data was reported in individual subject listings but not summarized.

End point values	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)	Placebo (Age Cohort: 12 to 16 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[19]	0[20]	0[21]	0[22]
Units: seizure				
number (not applicable)				

Notes:

[19] - Results not reported since the data was reported in individual subject listings but not summarized.
[20] - Results not reported since the data was reported in individual subject listings but not summarized.
[21] - Results not reported since the data was reported in individual subject listings but not summarized.
[22] - Results not reported since the data was reported in individual subject listings but not summarized.

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Curve From Time Zero to End of Dosing Interval (AUCtau): Multiple-Dose Analysis

End point title	Area Under the Curve From Time Zero to End of Dosing Interval (AUCtau): Multiple-Dose Analysis[23]

End point description:

Area under the curve from time zero to the end of dosing interval (AUCtau), where dosing interval was 12 hours, for subjects who received pregabalin from Day 1 to Day 8 morning is reported (multiple-dose subjects). Results are normalized to individual subject's Day 8 dose.
Pharmacokinetic (PK) parameter analysis population included all randomized and treated subjects who had at least 1 of the PK parameters of primary interest in at least 1 treatment period (double-blind or open label treatment). Geometric mean and geometric coefficient of variation (CV) obtained by sampling distribution of 2 subjects were not considered meaningful, hence not analyzed and represnted here as

99999. For number of subjects analyzed= 1, 99999 was reported in place of geometric CV as it was not evaluated.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1, 2, 4, 8, 12 hours post-dose on Day 8

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Multiple-Dose analysis was done only for those subjects who received multiple doses of pregabalin and thus excluded subjects assigned to placebo group.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[24]	3[25]	3[26]	2[27]
Units: (microgram*hour/milliliter)/(mg/kg)				
geometric mean (geometric coefficient of variation)	7.614 (± 19)	7.563 (± 26)	7.595 (± 6)	99999 (± 99999)

Notes:

[24] - Number of subjects analyzed 'N' signifies those subjects who were evaluable for the measure.

[25] - 'N' signifies those subjects who were evaluable for the measure.

[26] - 'N' signifies those subjects who were evaluable for the measure.

[27] - 'N' signifies those subjects who were evaluable for the measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[28]	2[29]	2[30]	3[31]
Units: (microgram*hour/milliliter)/(mg/kg)				
geometric mean (geometric coefficient of variation)	7.962 (± 29)	99999 (± 99999)	99999 (± 99999)	8.203 (± 31)

Notes:

[28] - 'N' signifies those subjects who were evaluable for the measure.

[29] - 'N' signifies those subjects who were evaluable for the measure.

[30] - 'N' signifies those subjects who were evaluable for the measure.

[31] - 'N' signifies those subjects who were evaluable for the measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[32]	3[33]	1[34]	2[35]
Units: (microgram*hour/milliliter)/(mg/kg)				
geometric mean (geometric coefficient of variation)	11.64 (± 29)	9.571 (± 9)	7.59 (± 99999)	99999 (± 99999)

Notes:

[32] - 'N' signifies those subjects who were evaluable for the measure.

[33] - 'N' signifies those subjects who were evaluable for the measure.

[34] - 'N' signifies those subjects who were evaluable for the measure.

[35] - 'N' signifies those subjects who were evaluable for the measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[36]	3[37]	4[38]	1[39]
Units: (microgram*hour/milliliter)/(mg/kg)				
geometric mean (geometric coefficient of variation)	10.2 (± 13)	13.07 (± 34)	9.642 (± 44)	14.4 (± 99999)

Notes:

[36] - 'N' signifies those subjects who were evaluable for the measure.

[37] - 'N' signifies those subjects who were evaluable for the measure.

[38] - 'N' signifies those subjects who were evaluable for the measure.

[39] - 'N' signifies those subjects who were evaluable for the measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Curve From Time Zero to Extrapolated Infinite Time [AUC (0 - ∞)]: Single-Dose Analysis

End point title	Area Under the Curve From Time Zero to Extrapolated Infinite Time [AUC (0 - ∞)]: Single-Dose Analysis

End point description:

AUC (0 - ∞)= Area under the plasma concentration versus time curve (AUC) from time zero (pre-dose) to extrapolated infinite time (0 - ∞). It is obtained from AUC (0 - t) plus AUC (t - ∞). AUC (0 - ∞) for subjects who received matching placebo from Day 1 to Day 7 and pregabalin on Day 8 morning is reported (single-dose subjects). Results are normalized to individual subject's Day 8 dose. PK parameter analysis population. Results are not reported for pregabalin 10 and 15 mg/kg/day for 12 to 16 age cohort since none of the subject had PK parameter available in these groups.
99999 is updated here in place geometric CV because number of subjects analysed was 1 and geometric CV cannot be evaluated.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1, 2, 4, 8, 12, 24 hours post-dose on Day 8

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 1 to 23 Months)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[40]	1[41]	1[42]	1[43]
Units: (microgram*hour/milliliter)/(mg/kg)				
geometric mean (geometric coefficient of variation)	6.7 (± 99999)	8.1 (± 99999)	7.05 (± 99999)	7.02 (± 99999)

Notes:

[40] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[41] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[42] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[43] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 2 to 6 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[44]	1[45]	1[46]	1[47]
Units: (microgram*hour/milliliter)/(mg/kg)				
geometric mean (geometric coefficient of variation)	8.3 (± 99999)	6.38 (± 99999)	8.76 (± 99999)	9.16 (± 99999)

Notes:
[44] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[45] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[46] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[47] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 7 to 11 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[48]	1[49]	1[50]	1[51]
Units: (microgram*hour/milliliter)/(mg/kg)				
geometric mean (geometric coefficient of variation)	10 (± 99999)	10.1 (± 99999)	8 (± 99999)	15.9 (± 99999)

Notes:
[48] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[49] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[50] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[51] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 12 to 16 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[52]	1[53]	0[54]	0[55]
Units: (microgram*hour/milliliter)/(mg/kg)				
geometric mean (geometric coefficient of variation)	13.8 (± 99999)	10.6 (± 99999)	()	()

Notes:
[52] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[53] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[54] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[55] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax): Multiple-Dose Analysis

End point title	Maximum Observed Plasma Concentration (Cmax): Multiple-Dose Analysis[56]

End point description:

Cmax for subjects who received pregabalin from Day 1 to Day 8 morning is reported (multiple-dose subjects). Results are normalized to
individual subject's Day 8 dose. PK parameter analysis population included all randomized and treated subjects who had at least 1 of the PK parameters of primary interest in at least 1 treatment period (double-blind or open label treatment). Geometric mean and geometric coefficient of variation obtained by sampling distribution of 2 subjects were not considered meaningful, hence not analyzed and represented here as 99999. For number of subjects analyzed= 1, 99999 was reported in place of geometric CV as it was not evaluated.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1, 2, 4, 8, 12, 24 hours post-dose on Day 8

Notes:

[56] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Multiple-Dose analysis was done only for those subjects who received multiple doses of pregabalin and thus excluded subjects assigned to placebo group.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[57]	3[58]	3[59]	2[60]
Units: microgram (mcg)/milliliter (mL)/(mg/kg)				
geometric mean (geometric coefficient of variation)	1.468 (± 23)	1.577 (± 11)	1.496 (± 14)	99999 (± 99999)

Notes:

[57] - Number of subjects analyzed 'N' signifies those subjects who were evaluable for the measure.

[58] - 'N' signifies those subjects who were evaluable for the measure.

[59] - 'N' signifies those subjects who were evaluable for the measure.

[60] - 'N' signifies those subjects who were evaluable for the measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[61]	2[62]	2[63]	3[64]
Units: microgram (mcg)/milliliter (mL)/(mg/kg)				
geometric mean (geometric coefficient of variation)	1.601 (± 13)	99999 (± 99999)	99999 (± 99999)	1.856 (± 15)

Notes:

[61] - 'N' signifies those subjects who were evaluable for the measure.

[62] - 'N' signifies those subjects who were evaluable for the measure.

[63] - 'N' signifies those subjects who were evaluable for the measure.

[64] - 'N' signifies those subjects who were evaluable for the measure.

End point values	Pregabalin 2.5	Pregabalin 5	Pregabalin 10	Pregabalin 15

	mg/kg/Day (Age Cohort: 7 to 11 Years)	mg/kg/Day (Age Cohort: 7 to 11 Years)	mg/kg/Day (Age Cohort: 7 to 11 Years)	mg/kg/Day (Age Cohort: 7 to 11 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[65]	3[66]	1[67]	2[68]
Units: microgram (mcg)/milliliter (mL)/(mg/kg)				
geometric mean (geometric coefficient of variation)	2.35 (± 29)	1.66 (± 13)	0.945 (± 99999)	99999 (± 99999)

Notes:

[65] - 'N' signifies those subjects who were evaluable for the measure.

[66] - 'N' signifies those subjects who were evaluable for the measure.

[67] - 'N' signifies those subjects who were evaluable for the measure.

[68] - 'N' signifies those subjects who were evaluable for the measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[69]	3[70]	4[71]	1[72]
Units: microgram (mcg)/milliliter (mL)/(mg/kg)				
geometric mean (geometric coefficient of variation)	1.762 (± 22)	2.538 (± 44)	1.355 (± 59)	1.94 (± 99999)

Notes:

[69] - 'N' signifies those subjects who were evaluable for the measure.

[70] - 'N' signifies those subjects who were evaluable for the measure.

[71] - 'N' signifies those subjects who were evaluable for the measure.

[72] - 'N' signifies those subjects who were evaluable for the measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax): Single-Dose Analysis

End point title	Maximum Observed Plasma Concentration (Cmax): Single-Dose Analysis

End point description:

Cmax for subjects who received matching placebo from Day 1 to Day 7 and pregabalin on Day 8 morning is reported (single-dose subjects). Results are normalized to individual subject's Day 8 dose. PK parameter analysis population. Results are not reported for pregabalin 10 and 15 mg/kg/day for 12 to 16 age cohort since none of the subject had PK parameter available in these groups. 99999 is updated here in place geometric CV because number of subjects analysed was 1 and geometric CV cannot be evaluated.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1, 2, 4, 8, 12, 24 hours post-dose on Day 8

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 1 to 23 Months)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[73]	1[74]	1[75]	1[76]
Units: (mcg/mL)/(mg/kg)				
geometric mean (geometric coefficient of variation)	1.51 (± 99999)	1.81 (± 99999)	1.18 (± 99999)	1.52 (± 99999)

Notes:

[73] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[74] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[75] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[76] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 2 to 6 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[77]	1[78]	1[79]	1[80]
Units: (mcg/mL)/(mg/kg)				
geometric mean (geometric coefficient of variation)	1.93 (± 99999)	1.5 (± 99999)	1.7 (± 99999)	1.54 (± 99999)

Notes:

[77] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[78] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[79] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[80] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 7 to 11 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[81]	1[82]	1[83]	1[84]
Units: (mcg/mL)/(mg/kg)				
geometric mean (geometric coefficient of variation)	1.31 (± 99999)	2.29 (± 99999)	1.24 (± 99999)	1.28 (± 99999)

Notes:

[81] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[82] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[83] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[84] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 12 to 16 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[85]	1[86]	0[87]	0[88]
Units: (mcg/mL)/(mg/kg)				
geometric mean (geometric coefficient of variation)	1.81 (± 99999)	1.79 (± 99999)	()	()

Notes:

[85] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[86] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[87] - For pregabalin 10 mg/kg/day for 12 to 16 age cohort no subject had PK parameter available.

[88] - For pregabalin 15 mg/kg/day for 12 to 16 age cohort no subject had PK parameter available.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Reach Maximum Observed Plasma Concentration (Tmax): Multiple-Dose Analysis

End point title	Time to Reach Maximum Observed Plasma Concentration (Tmax): Multiple-Dose Analysis[89]

End point description:

Tmax for subjects who received pregabalin from Day 1 to Day 8 morning is reported (multiple-dose subjects). PK parameter analysis population included all randomized and treated subjects who had at least 1 of the PK parameters of primary interest in at least 1 treatment period (double-blind or open label treatment).

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1, 2, 4, 8, 12, 24 hours post-dose on Day 8

Notes:

[89] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Multiple-Dose analysis was done only for those subjects who received multiple doses of pregabalin and thus excluded subjects assigned to placebo group.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[90]	3[91]	3[92]	2[93]
Units: hours				
median (full range (min-max))	0.617 (0.5 to 1)	1.05 (1 to 2.08)	1.12 (1.02 to 2)	2.49 (0.967 to 4.02)

Notes:

[90] - Number of subjects analyzed 'N' signifies those subjects who were evaluable for the measure.

[91] - 'N' signifies those subjects who were evaluable for the measure.

[92] - 'N' signifies those subjects who were evaluable for the measure.

[93] - 'N' signifies those subjects who were evaluable for the measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[94]	2[95]	2[96]	3[97]
Units: hours				
median (full range (min-max))	0.5 (0.5 to 2)	1.67 (1.17 to 2.17)	2.62 (1.17 to 4.07)	1 (0.967 to 1.17)

Notes:

[94] - 'N' signifies those subjects who were evaluable for the measure.

[95] - 'N' signifies those subjects who were evaluable for the measure.

[96] - 'N' signifies those subjects who were evaluable for the measure.

[97] - 'N' signifies those subjects who were evaluable for the measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[98]	3[99]	1[100]	2[101]
Units: hours				
median (full range (min-max))	0.583 (0.583 to 1)	1 (1 to 1)	4 (4 to 4)	0.79 (0.5 to 1.08)

Notes:

[98] - 'N' signifies those subjects who were evaluable for the measure.

[99] - 'N' signifies those subjects who were evaluable for the measure.

[100] - 'N' signifies those subjects who were evaluable for the measure.

[101] - 'N' signifies those subjects who were evaluable for the measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[102]	3[103]	4[104]	1[105]
Units: hours				
median (full range (min-max))	0.5 (0.5 to 4)	0.583 (0.483 to 1)	2.09 (1.5 to 8.08)	2.15 (2.15 to 2.15)

Notes:

[102] - 'N' signifies those subjects who were evaluable for the measure.

[103] - 'N' signifies those subjects who were evaluable for the measure.

[104] - 'N' signifies those subjects who were evaluable for the measure.

[105] - 'N' signifies those subjects who were evaluable for the measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Reach Maximum Observed Plasma Concentration (Tmax): Single-Dose Analysis

End point title	Time to Reach Maximum Observed Plasma Concentration (Tmax): Single-Dose Analysis

End point description:

Tmax for subjects who received matching placebo from Day 1 to Day 7 and pregabalin on Day 8 morning is reported (single-dose subjects).
PK parameter analysis population. Results are not reported for pregabalin 10 and 15 mg/kg/day for 12 to 16 age cohort since none of the subject had PK parameter available in these groups.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1, 2, 4, 8, 12, 24 hours post-dose on Day 8

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 1 to 23 Months)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	1	1
Units: hours				
median (full range (min-max))	1 (1 to 1)	0.967 (0.967 to 0.967)	1.13 (1.13 to 1.13)	1 (1 to 1)

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 2 to 6 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	1	1
Units: hours				
median (full range (min-max))	0.45 (0.45 to 0.45)	1 (1 to 1)	1 (1 to 1)	1.98 (1.98 to 1.98)

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 7 to 11 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	1	1
Units: hours				
median (full range (min-max))	1 (1 to 1)	0.583 (0.583 to 0.583)	2 (2 to 2)	4 (4 to 4)

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 12 to 16 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1	1	0[106]	0[107]
Units: hours				
median (full range (min-max))	4.05 (4.05 to 4.05)	1 (1 to 1)	(to)	(to)

Notes:

[106] - For pregabalin 10 mg/kg/day for 12 to 16 age cohort no subject had PK parameter available.

[107] - For pregabalin 15 mg/kg/day for 12 to 16 age cohort no subject had PK parameter available.

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Decay Half-Life (t1/2): Multiple-Dose Analysis

End point title	Plasma Decay Half-Life (t1/2): Multiple-Dose Analysis[108]

End point description:

Plasma decay half-life is the time measured for the plasma concentration to decrease by one half. t1/2 for subjects who received pregabalin from Day 1 to Day 8 morning is reported (multiple-dose subjects). PK parameter analysis population included all randomized and treated subjects who had at least 1 of the PK parameters of primary interest in at least 1 treatment period (double-blind or open label treatment). Arithmetic mean and standard deviation obtained by sampling distribution of 2 subjects were not considered meaningful, hence not analyzed and represnted here as 99999. For reporting arms where number of subjects= 1, standard deviation is represented as 99999.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1, 2, 4, 8, 12, 24 hours post-dose on Day 8

Notes:

[108] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Multiple-Dose analysis was done only for those subjects who received multiple doses of pregabalin and thus excluded subjects assigned to placebo group.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[109]	3[110]	3[111]	2[112]
Units: hours				
arithmetic mean (standard deviation)	4.433 (± 0.17559)	3.397 (± 0.58603)	3.263 (± 0.49903)	99999 (± 99999)

Notes:

[109] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[110] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[111] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[112] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[113]	2[114]	3[115]	3[116]
Units: hours				
arithmetic mean (standard deviation)	3.9 (± 99999)	99999 (± 99999)	3.523 (± 0.25146)	3.52 (± 0.91804)

Notes:

[113] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[114] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[115] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[116] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[117]	3[118]	2[119]	2[120]
Units: hours				
arithmetic mean (standard deviation)	4.287 (± 0.27737)	4.113 (± 0.25891)	99999 (± 99999)	99999 (± 99999)

Notes:

[117] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[118] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[119] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[120] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[121]	3[122]	4[123]	1[124]
Units: hours				
arithmetic mean (standard deviation)	4.96 (± 1.3857)	3.953 (± 0.80532)	5.643 (± 0.88921)	6.61 (± 99999)

Notes:

[121] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[122] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[123] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[124] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Plasma Decay Half-Life (t1/2): Single-Dose Analysis

End point title	Plasma Decay Half-Life (t1/2): Single-Dose Analysis

End point description:

Plasma decay half-life is the time measured for the plasma concentration to decrease by one half. t1/2 for subjects who received matching placebo from Day 1 to Day 7 and pregabalin on Day 8 morning is reported (single-dose subjects). PK parameter analysis population. Results are not reported for pregabalin 10 and 15 mg/kg/day for 12 to 16 age cohort since none of the subject had PK parameter available in these groups. Number of subjects analzed were only 1, standard deviation was not evaluated and represented here as 99999.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1, 2, 4, 8, 12, 24 hours post-dose on Day 8

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 1 to 23 Months)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[125]	1[126]	1[127]	1[128]
Units: hours				
arithmetic mean (standard deviation)	2.64 (± 99999)	3.78 (± 99999)	3.76 (± 99999)	3.22 (± 99999)

Notes:
[125] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[126] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[127] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[128] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 2 to 6 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[129]	1[130]	1[131]	1[132]
Units: hours				
arithmetic mean (standard deviation)	3.88 (± 99999)	2.7 (± 99999)	3.83 (± 99999)	3.08 (± 99999)

Notes:
[129] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[130] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[131] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[132] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 7 to 11 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[133]	1[134]	1[135]	1[136]
Units: hours				
arithmetic mean (standard deviation)	4.77 (± 99999)	4.02 (± 99999)	3.13 (± 99999)	6.54 (± 99999)

Notes:
[133] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[134] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[135] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[136] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 12 to 16 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[137]	1[138]	0[139]	0[140]
Units: hours				
arithmetic mean (standard deviation)	5.8 (± 99999)	3.85 (± 99999)	()	()

Notes:
[137] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[138] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.
[139] - For pregabalin 10 mg/kg/day for 12 to 16 age cohort no subject had PK parameter available.
[140] - For pregabalin 15 mg/kg/day for 12 to 16 age cohort no subject had PK parameter available.

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Oral Clearance (CL/F): Multiple-Dose Analysis

End point title	Apparent Oral Clearance (CL/F): Multiple-Dose Analysis[141]

End point description:

Clearance (CL) of a drug is a measure of the rate at which a drug is metabolized or eliminated by normal biological processes. Clearance obtained after oral dose (apparent oral clearance) is influenced by the fraction of the dose absorbed (F). Drug clearance is a quantitative measure of the rate at which a drug substance is removed from the blood. CL/F for subjects who received pregabalin from Day 1 to Day 8 morning is reported (multiple-dose subjects). PK parameter analysis population included all randomized and treated subjects who had at least 1 of the PK parameters of primary interest in at least 1 treatment period (double-blind or open label treatment). Geometric mean and geometric coefficient of variation obtained by sampling distribution of 2 subjects were not considered meaningful, hence not analyzed and represented here as 99999. For reporting arms where number of subjects= 1, standard deviation is represented as 99999.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1, 2, 4, 8, 12, 24 hours post-dose on Day 8

Notes:

[141] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Multiple-Dose analysis was done only for those subjects who received multiple doses of pregabalin and thus excluded subjects assigned to placebo group.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[142]	3[143]	3[144]	2[145]
Units: milliliter/minute (mL/min)				
geometric mean (geometric coefficient of variation)	19 (± 10)	17.7 (± 47)	18.54 (± 49)	99999 (± 99999)

Notes:

[142] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[143] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[144] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[145] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[146]	2[147]	2[148]	3[149]
Units: milliliter/minute (mL/min)				
geometric mean (geometric coefficient of variation)	34.18 (± 61)	99999 (± 99999)	99999 (± 99999)	30.49 (± 9)

Notes:

[146] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[147] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[148] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[149] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[150]	3[151]	1[152]	2[153]
Units: milliliter/minute (mL/min)				

geometric mean (geometric coefficient of variation)	58.23 (± 42)	49.49 (± 19)	63.7 (± 99999)	99999 (± 99999)

Notes:

[150] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[151] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[152] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[153] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3[154]	3[155]	4[156]	1[157]
Units: milliliter/minute (mL/min)				
geometric mean (geometric coefficient of variation)	90.56 (± 26)	78.38 (± 12)	85.87 (± 17)	73.1 (± 99999)

Notes:

[154] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[155] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[156] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[157] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Oral Clearance (CL/F): Single-Dose Analysis

End point title	Apparent Oral Clearance (CL/F): Single-Dose Analysis

End point description:

Clearance (CL) of a drug is a measure of the rate at which a drug is metabolized or eliminated by normal biological processes. Clearance obtained after oral dose (apparent oral clearance) is influenced by the fraction of the dose absorbed (F). Drug clearance is a quantitative measure of the rate at which a drug substance is removed from the blood. CL/F for subjects who received matching placebo from Day 1 to Day 7 and pregabalin on Day 8 morning is reported (single-dose subjects). PK parameter analysis population. Results are not reported for pregabalin 10 and 15 mg/kg/day for 12 to 16 age cohort since none of the subject had PK parameter available in these groups. 99999 is updated here in place geometric CV because number of subjects analysed was 1 and geometric CV cannot be evaluated.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 1, 2, 4, 8, 12, 24 hours post-dose on Day 8

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 1 to 23 Months)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[158]	1[159]	1[160]	1[161]
Units: mL/min				
geometric mean (geometric coefficient of variation)	31.5 (± 99999)	24.7 (± 99999)	20.1 (± 99999)	28 (± 99999)

Notes:

[158] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[159] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[160] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[161] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 2 to 6 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[162]	1[163]	1[164]	1[165]
Units: mL/min				
geometric mean (geometric coefficient of variation)	32.3 (± 99999)	60.1 (± 99999)	38.8 (± 99999)	45.5 (± 99999)

Notes:

[162] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[163] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[164] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[165] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 7 to 11 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[166]	1[167]	1[168]	1[169]
Units: mL/min				
geometric mean (geometric coefficient of variation)	58.2 (± 99999)	45.8 (± 99999)	64.8 (± 99999)	54.3 (± 99999)

Notes:

[166] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[167] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[168] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[169] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 12 to 16 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	1[170]	1[171]	0[172]	0[173]
Units: mL/min				
geometric mean (geometric coefficient of variation)	99.6 (± 99999)	90 (± 99999)	()	()

Notes:

[170] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[171] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[172] - For pregabalin 10 mg/kg/day for 12 to 16 age cohort no subject had PK parameter available.

[173] - For pregabalin 15 mg/kg/day for 12 to 16 age cohort no subject had PK parameter available.

Statistical analyses

No statistical analyses for this end point

Secondary: Renal Clearance (CLr): Multiple-Dose Analysis

End point title	Renal Clearance (CLr): Multiple-Dose Analysis[174]

End point description:

Renal clearance is the volume of plasma from which the drug is completely removed by the kidney in a given amount of time. CLr for subjects who received pregabalin from Day 1 to Day 8 morning is reported (multiple-dose subjects). PK parameter analysis population. Results are not reported for some of the groups since none of the subject had PK parameter available in these groups. Geometric mean and geometric CV obtained by sampling distribution of 2 subjects were not considered meaningful, hence not analyzed and represented here as 99999. For number of subjects analyzed= 1, 99999 was reported in place of geometric CV as it was not evaluated.

End point type	Secondary

End point timeframe:

0 to 12 hours post-dose, 12 to 24 hours post-dose on Day 8

Notes:

[174] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Multiple-Dose analysis was done only for those subjects who received multiple doses of pregabalin and thus excluded subjects assigned to placebo group.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[175]	1[176]	0[177]	0[178]
Units: mL/min				
geometric mean (geometric coefficient of variation)	()	21 (± 99999)	()	()

Notes:

[175] - Results are not reported as none of the subject had PK parameter available in this group.

[176] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[177] - Results are not reported as none of the subject had PK parameter available in this group.

[178] - Results are not reported as none of the subject had PK parameter available in this group.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1[179]	0[180]	1[181]	1[182]
Units: mL/min				
geometric mean (geometric coefficient of variation)	8.77 (± 99999)	()	48.4 (± 99999)	11.5 (± 99999)

Notes:

[179] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[180] - Results are not reported as none of the subject had PK parameter available in this group.

[181] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[182] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[183]	3[184]	1[185]	1[186]
Units: mL/min				
geometric mean (geometric coefficient of variation)	()	24.75 (± 88)	55.9 (± 99999)	36.9 (± 99999)

Notes:

[183] - Results are not reported as none of the subject had PK parameter available in this group.

[184] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[185] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[186] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[187]	2[188]	3[189]	0[190]
Units: mL/min				
geometric mean (geometric coefficient of variation)	()	99999 (± 99999)	69.16 (± 39)	()

Notes:

[187] - Results are not reported as none of the subject had PK parameter available in this group.

[188] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[189] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[190] - Results are not reported as none of the subject had PK parameter available in this group.

Statistical analyses

No statistical analyses for this end point

Secondary: Renal Clearance (CLr): Single-Dose Analysis

End point title	Renal Clearance (CLr): Single-Dose Analysis

End point description:

Renal clearance is the volume of plasma from which the drug is completely removed by the kidney in a given amount of time. CLr for subjects who received matching placebo from Day 1 to Day 7 and pregabalin on Day 8 morning was to be reported (single-dose subjects). PK parameter analysis population. Results are only reported for pregabalin 15 mg/kg/day, 7 to 11 years and pregabalin 5 mg/kg/day, 12 to 16 years because none of the subject had PK parameter available in rest of the groups. For number of subjects analyzed= 1, 99999 was reported in place of geometric CV as it was not evaluated.

End point type	Secondary

End point timeframe:

0 to 12 hours post-dose, 12 to 24 hours post-dose on Day 8

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 1 to 23 Months)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 1 to 23 Months)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[191]	0[192]	0[193]	0[194]
Units: mL/min				
geometric mean (geometric coefficient of variation)	()	()	()	()

Notes:

[191] - Results are not reported as none of the subject had PK parameter available in this group.

[192] - Results are not reported as none of the subject had PK parameter available in this group.

[193] - Results are not reported as none of the subject had PK parameter available in this group.

[194] - Results are not reported as none of the subject had PK parameter available in this group.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 2 to 6 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 2 to 6 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[195]	0[196]	0[197]	0[198]
Units: mL/min				
geometric mean (geometric coefficient of variation)	()	()	()	()

Notes:

[195] - Results are not reported as none of the subject had PK parameter available in this group.

[196] - Results are not reported as none of the subject had PK parameter available in this group.

[197] - Results are not reported as none of the subject had PK parameter available in this group.

[198] - Results are not reported as none of the subject had PK parameter available in this group.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 7 to 11 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 7 to 11 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[199]	0[200]	0[201]	1[202]
Units: mL/min				
geometric mean (geometric coefficient of variation)	()	()	()	42.6 (± 99999)

Notes:

[199] - Results are not reported as none of the subject had PK parameter available in this group.

[200] - Results are not reported as none of the subject had PK parameter available in this group.

[201] - Results are not reported as none of the subject had PK parameter available in this group.

[202] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

End point values	Placebo, Pregabalin 1.25 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 2.5 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 5 mg/kg (Age Cohort: 12 to 16 Years)	Placebo, Pregabalin 7.5 mg/kg (Age Cohort: 12 to 16 Years)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[203]	1[204]	0[205]	0[206]
Units: mL/min				
geometric mean (geometric coefficient of variation)	()	73.8 (± 99999)	()	()

Notes:

[203] - Results are not reported as none of the subject had PK parameter available in this group.

[204] - 'N' (number of subjects analyzed) signifies those subjects who were evaluable for this measure.

[205] - Results are not reported as none of the subject had PK parameter available in this group.

[206] - Results are not reported as none of the subject had PK parameter available in this group.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events (AE) (serious and nonserious) were to be recorded from the time the subject provided consent to participate in the study through the last subject visit.

Adverse event reporting additional description:

The same event may appear as both an AE and a serious adverse event(SAE). However, what is presented are distinct events. An event may be categorized as serious in one subject and as nonserious in another subject, or one subject may have experienced both a serious and nonserious event during the study. Latest coding was used to generate AEs tables.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation as double blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administerd. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received pregabalin oral liquid formulation as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Placebo (Age Cohort: 1 to 23 Months)

Reporting group description:

Subjects of 1 to 23 months of age received placebo matched to pregabalin oral liquid formulation as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation of different doses were administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered. Subjects who

discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received pregabalin oral liquid formulation as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Placebo (Age Cohort: 2 to 6 Years)

Reporting group description:

Subjects of 2 to 6 years of age received placebo matched to pregabalin oral liquid formulation as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation of different doses were administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received pregabalin oral liquid formulation as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received pregabalin oral liquid formulation as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was aadministered .Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received pregabalin oral capsule as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received pregabalin oral capsule as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Placebo (Age Cohort: 7 to 11 Years)

Reporting group description:

Subjects of 7 to 11 years of age received placebo matched to pregabalin oral liquid formulation or capsule as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation or pregabalin oral capsule of different doses were administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received pregabalin oral liquid formulation as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received pregabalin oral liquid formulation as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation was administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received pregabalin oral capsule as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received pregabalin oral capsule as double-blind treatment. Single open-label morning dose of pregabalin oral capsule was administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Reporting group title	Placebo (Age Cohort: 12 to 16 Years)

Reporting group description:

Subjects of 12 to 16 years of age received placebo matched to pregabalin oral liquid formulation or capsule as double-blind treatment. Single open-label morning dose of pregabalin oral liquid formulation or pregabalin oral capsule of different doses were administered. Subjects who discontinued or did not enter open-label extension study were tapered off medication over 1 week.

Serious adverse events	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (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
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (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	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)	Placebo (Age Cohort: 1 to 23 Months)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (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	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (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
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (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	Placebo (Age Cohort: 2 to 6 Years)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			

Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (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			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (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
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (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	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)	Placebo (Age Cohort: 7 to 11 Years)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 5 (20.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 5 (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
Convulsion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 5 (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

Serious adverse events	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16

	Years)	Years)	Years)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (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			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (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
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (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	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)	Placebo (Age Cohort: 12 to 16 Years)	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Convulsion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Pregabalin 2.5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 5 mg/kg/Day (Age Cohort: 1 to 23 Months)	Pregabalin 10 mg/kg/Day (Age Cohort: 1 to 23 Months)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	1 / 3 (33.33%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Snoring			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Learning disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Electrocardiogram abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1

Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tandem gait test abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Convulsion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drooling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mental impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nystagmus			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sedation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Speech disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Mydriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			

Dermatitis contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Otitis media			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Pregabalin 15 mg/kg/Day (Age Cohort: 1 to 23 Months)	Placebo (Age Cohort: 1 to 23 Months)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 2 to 6 Years)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	2 / 4 (50.00%)	2 / 4 (50.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Snoring			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Irritability			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Learning disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Electrocardiogram abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tandem gait test abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			

Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Convulsion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Drooling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mental impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nystagmus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sedation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Somnolence			
subjects affected / exposed	2 / 3 (66.67%)	2 / 4 (50.00%)	1 / 4 (25.00%)
occurrences (all)	3	2	1
Speech disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Mydriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Rash			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Otitis media			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Pregabalin 5 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 2 to 6 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 2 to 6 Years)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	2 / 3 (66.67%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Snoring			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Learning disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Electrocardiogram abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Tandem gait test abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Convulsion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Drooling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Lethargy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Mental impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nystagmus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sedation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Speech disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Mydriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Infections and infestations			
Otitis media			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Placebo (Age Cohort: 2 to 6 Years)	Pregabalin 2.5 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 7 to 11 Years)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 5 (80.00%)	2 / 3 (66.67%)	3 / 3 (100.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	2 / 5 (40.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Rhonchi			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Sinus congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Snoring			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Wheezing			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Irritability			

subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Learning disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Electrocardiogram abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tandem gait test abnormal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Balance disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Convulsion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drooling			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypersomnia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Mental impairment			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nystagmus			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Psychomotor hyperactivity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sedation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	2 / 3 (66.67%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Speech disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Mydriasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 5 (40.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Dry mouth			

subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Otitis media			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			

subjects affected / exposed	1 / 5 (20.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 5 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Pregabalin 10 mg/kg/Day (Age Cohort: 7 to 11 Years)	Pregabalin 15 mg/kg/Day (Age Cohort: 7 to 11 Years)	Placebo (Age Cohort: 7 to 11 Years)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	2 / 3 (66.67%)	2 / 5 (40.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Feeling abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Snoring			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Irritability			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Learning disorder			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Investigations			

Electrocardiogram abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tandem gait test abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Convulsion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	2 / 3 (66.67%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Drooling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	1 / 5 (20.00%)
occurrences (all)	0	2	2
Hypersomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	1 / 5 (20.00%)
occurrences (all)	1	0	1
Mental impairment			

subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Nystagmus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychomotor hyperactivity			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Sedation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Speech disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Mydriasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	1 / 3 (33.33%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vomiting			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Otitis media			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Viral infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Decreased appetite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Pregabalin 2.5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 5 mg/kg/Day (Age Cohort: 12 to 16 Years)	Pregabalin 10 mg/kg/Day (Age Cohort: 12 to 16 Years)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	4 / 4 (100.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Feeling abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			

Seasonal allergy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhonchi			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Snoring			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Learning disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Electrocardiogram abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Tandem gait test abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Convulsion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Drooling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypersomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mental impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nystagmus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Psychomotor hyperactivity			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sedation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Somnolence			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Speech disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Eye disorders			
Mydriasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis diaper			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Otitis media			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Subcutaneous abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Pregabalin 15 mg/kg/Day (Age Cohort: 12 to 16 Years)	Placebo (Age Cohort: 12 to 16 Years)	
Total subjects affected by non-serious adverse events			

subjects affected / exposed	2 / 2 (100.00%)	0 / 3 (0.00%)	
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Feeling abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Oedema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Peripheral swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Rhonchi			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Sinus congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Snoring			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Irritability			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Learning disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Investigations			
Electrocardiogram abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Tandem gait test abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Balance disorder			

subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
Convulsion				
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Dizziness				
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
Drooling				
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Headache				
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Hypersomnia				
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Lethargy				
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Mental impairment				
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Nystagmus				
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Psychomotor hyperactivity				
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Sedation				
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)		
occurrences (all)	0	0		
Somnolence				
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)		
occurrences (all)	1	0		
Speech disorder				

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Mydriasis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Vomiting			
subjects affected / exposed	1 / 2 (50.00%)	0 / 3 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Dermatitis diaper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Pruritus			

subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Otitis media			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Subcutaneous abscess			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Viral infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 3 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 January 2010	1. Reduction in the number of subjects in the 1 to 23 month age cohorts from 8/dose level to 4/dose level.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Results are reported for AUCtau for multiple-dose PK analysis and AUC (0-∞) for single-dose PK analysis, instead of AUC (0-24), as per change in planned analysis.

Notes: