



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 | Subject, Investigator, Carer, Assessor |

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 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 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.

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 |

Baseline characteristics

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 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: 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 standard deviation | 1.2 ± 0.7 | 1.4 ± 0.5 | 0.7 ± 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 standard deviation | 0.6 ± 0.1 | 1.6 ± 0.3 | 4 ± 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 standard deviation | 2.9 ± 0.1 | 4 ± 1.7 | 3.9 ± 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 standard deviation | 15.5 ± 0.7 | 13 ± 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 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: 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.

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

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 (AUC_{tau}): Multiple-Dose Analysis

| | |
|-----------------|---|
| End point title | Area Under the Curve From Time Zero to End of Dosing Interval (AUC _{tau}): Multiple-Dose Analysis ^[23] |
|-----------------|---|

End point description:

Area under the curve from time zero to the end of dosing interval (AUC_{tau}), 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 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 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

Secondary: Maximum Observed Plasma Concentration (C_{max}): Multiple-Dose Analysis

| | |
|-----------------|---|
| End point title | Maximum Observed Plasma Concentration (C _{max}): Multiple-Dose Analysis ^[56] |
|-----------------|---|

End point description:

C_{max} 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

Secondary: Plasma Decay Half-Life (t_{1/2}): Multiple-Dose Analysis

| | |
|--|---|
| End point title | Plasma Decay Half-Life (t _{1/2}): Multiple-Dose Analysis ^[108] |
| End point description: | |
| Plasma decay half-life is the time measured for the plasma concentration to decrease by one half. t _{1/2} 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 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:

[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 (t_{1/2}): Single-Dose Analysis

| | |
|--|--|
| End point title | Plasma Decay Half-Life (t _{1/2}): Single-Dose Analysis |
| End point description: | |
| Plasma decay half-life is the time measured for the plasma concentration to decrease by one half. t _{1/2} 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 analyzed 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

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

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

| | | | |
|---|---------------------|---------------------|--------------------|
| Platelet count decreased subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Tandem gait test abnormal subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Nervous system disorders | | | |
| Ataxia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 1 / 3 (33.33%) 1 | 0 / 3 (0.00%) 0 |
| Balance disorder subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Convulsion subjects affected / exposed occurrences (all) | 1 / 3 (33.33%) 1 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Dizziness subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Drooling subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Headache subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Hypersomnia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Lethargy subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Mental impairment subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 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 occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Dermatitis diaper subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Erythema subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Rash subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Pruritus subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Muscular weakness subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Infections and infestations Otitis media subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Subcutaneous abscess subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Viral infection subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 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 occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| General disorders and administration site conditions Chest pain subjects affected / exposed occurrences (all) Fatigue subjects affected / exposed occurrences (all) Feeling abnormal subjects affected / exposed occurrences (all) Gait disturbance subjects affected / exposed occurrences (all) Oedema subjects affected / exposed occurrences (all) Peripheral swelling subjects affected / exposed occurrences (all) Pyrexia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 0 / 4 (0.00%) 0 |
| Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders | | | |

| | | | |
|--|---------------------|---------------------|--------------------|
| Nasal congestion subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Rhonchi subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Sinus congestion subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Snoring subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Wheezing subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Psychiatric disorders | | | |
| Insomnia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 1 / 4 (25.00%) 1 | 0 / 4 (0.00%) 0 |
| Irritability subjects affected / exposed occurrences (all) | 1 / 3 (33.33%) 1 | 1 / 4 (25.00%) 1 | 0 / 4 (0.00%) 0 |
| Learning disorder subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Investigations | | | |
| Electrocardiogram abnormal subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Platelet count decreased subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Tandem gait test abnormal subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 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 occurrences (all) | 2 / 3 (66.67%) 3 | 2 / 4 (50.00%) 2 | 1 / 4 (25.00%) 1 |
| Speech disorder subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Eye disorders Mydriasis subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all) | 1 / 3 (33.33%) 0 | 0 / 4 (0.00%) 0 | 1 / 4 (25.00%) 1 |
| Diarrhoea subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Dry mouth subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Nausea subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Vomiting subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Skin and subcutaneous tissue disorders Dermatitis contact subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Dermatitis diaper subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Erythema subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 1 / 4 (25.00%) 1 | 0 / 4 (0.00%) 0 |
| Rash | | | |

| | | | |
|--|---------------------|--------------------|--------------------|
| subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Pruritus subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders Muscular weakness subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Infections and infestations Otitis media subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Subcutaneous abscess subjects affected / exposed occurrences (all) | 1 / 3 (33.33%) 1 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Viral infection subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 | 0 / 4 (0.00%) 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 occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 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 occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Wheezing subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Psychiatric disorders Insomnia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Irritability subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 3 (33.33%) 1 |
| Learning disorder subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Investigations Electrocardiogram abnormal subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Platelet count decreased subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 3 (33.33%) 1 |
| Tandem gait test abnormal subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Nervous system disorders Ataxia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 3 (33.33%) 1 |
| Balance disorder subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Convulsion subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 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 occurrences (all) | 1 / 3 (33.33%) 1 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Subcutaneous abscess subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Viral infection subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 1 / 3 (33.33%) 1 | 0 / 3 (0.00%) 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 occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| General disorders and administration site conditions Chest pain subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Fatigue subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Feeling abnormal subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Gait disturbance | | | |

| | | | |
|---|---------------------|--------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Oedema subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Peripheral swelling subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Pyrexia subjects affected / exposed occurrences (all) | 2 / 5 (40.00%) 2 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 3 (33.33%) 1 |
| Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Rhonchi subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Sinus congestion subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 3 (33.33%) 1 |
| Snoring subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Wheezing subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Psychiatric disorders Insomnia subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 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 occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Nausea subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Vomiting subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Skin and subcutaneous tissue disorders | | | |
| Dermatitis contact subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Dermatitis diaper subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Erythema subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Rash subjects affected / exposed occurrences (all) | 1 / 5 (20.00%) 1 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Pruritus subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Muscular weakness subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Infections and infestations | | | |
| Otitis media subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 |
| Subcutaneous abscess subjects affected / exposed occurrences (all) | 0 / 5 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 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 occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Pyrexia subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Rhonchi subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Sinus congestion subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Snoring subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Wheezing subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Psychiatric disorders Insomnia subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 3 (33.33%) 1 | 0 / 5 (0.00%) 0 |
| Irritability subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Learning disorder subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 3 (33.33%) 1 | 0 / 5 (0.00%) 0 |
| Investigations | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| Electrocardiogram abnormal subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Platelet count decreased subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Tandem gait test abnormal subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Nervous system disorders | | | |
| Ataxia subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Balance disorder subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Convulsion subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Dizziness subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 2 / 3 (66.67%) 2 | 0 / 5 (0.00%) 0 |
| Drooling subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Headache subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 1 / 3 (33.33%) 2 | 1 / 5 (20.00%) 2 |
| Hypersomnia subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 0 |
| Lethargy subjects affected / exposed occurrences (all) | 1 / 2 (50.00%) 1 | 0 / 3 (0.00%) 0 | 1 / 5 (20.00%) 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 occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 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 occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 5 (0.00%) 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 occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 4 (25.00%) 1 |
| General disorders and administration site conditions Chest pain subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 4 (25.00%) 1 |
| Fatigue subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 4 (25.00%) 1 |
| Feeling abnormal subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 4 (25.00%) 1 |
| Gait disturbance subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 4 (25.00%) 1 |
| Oedema subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Peripheral swelling subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Pyrexia subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 1 / 3 (33.33%) 1 | 0 / 4 (0.00%) 0 |
| Immune system disorders | | | |

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

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

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

| | | | |
|--|--------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Erythema subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Rash subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 4 (25.00%) 1 |
| Pruritus subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 1 / 4 (25.00%) 1 |
| Musculoskeletal and connective tissue disorders Muscular weakness subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Infections and infestations Otitis media subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Subcutaneous abscess subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Upper respiratory tract infection subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 0 |
| Viral infection subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 1 / 3 (33.33%) 1 | 0 / 4 (0.00%) 0 |
| Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all) | 0 / 3 (0.00%) 0 | 0 / 3 (0.00%) 0 | 0 / 4 (0.00%) 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 occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | |
| Sinus congestion subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | |
| Snoring subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | |
| Wheezing subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | |
| Psychiatric disorders Insomnia subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | |
| Irritability subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | |
| Learning disorder subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | |
| Investigations Electrocardiogram abnormal subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | |
| Platelet count decreased subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | |
| Tandem gait test abnormal subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | |
| Nervous system disorders Ataxia subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 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 | |
| Droling | | | |
| 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 occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | |
| Eye disorders Mydriasis subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 | |
| Gastrointestinal disorders Constipation subjects affected / exposed occurrences (all) Diarrhoea subjects affected / exposed occurrences (all) Dry mouth subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all) | 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0 1 / 2 (50.00%) 1 1 / 2 (50.00%) 1 | 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 | |
| Skin and subcutaneous tissue disorders Dermatitis contact subjects affected / exposed occurrences (all) Dermatitis diaper subjects affected / exposed occurrences (all) Erythema subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all) Pruritus | 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0 0 / 2 (0.00%) 0 | 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 0 / 3 (0.00%) 0 | |

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