Safety and Effectiveness of Open-Label Clobazam in Subjects With Lennox-Gastaut Syndrome (LGS)

This study has been completed.

Sponsor:
Lundbeck LLC

Information provided by (Responsible Party):
Lundbeck LLC

ClinicalTrials.gov Identifier:
NCT01160770

First received: June 18, 2010
Last updated: March 22, 2013
Last verified: March 2013
History of Changes

Results First Received: February 15, 2013

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Lennox-Gastaut Syndrome
Intervention:	Drug: Clobazam

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
Subjects enrolled in the LGS studies 13108A/OV1002/NCT00162981 or 13110A/OV1012/NCT00518713 sponsored by Lundbeck LLC who either completed the study or who prematurely discontinued will have the opportunity to rollover into this open-label study.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
Clobazam	Start dose was 0.5 mg/kg with a maximum of 40 mg/day to be adjusted; administered as tablets twice daily

Participant Flow: Overall Study

	Clobazam
STARTED	**267**
COMPLETED	**188**
NOT COMPLETED	**79**
Adverse Event	**10**
Protocol Violation	**2**
Subject/parent/caregiver request	**33**
Physician Decision	**1**
Lost to Follow-up	**7**
Study termination or sponsor request	**1**
Death	**9**
Lack of Efficacy	**15**
Other Reasons	**1**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Clobazam	Start dose was 0.5 mg/kg with a maximum of 40 mg/day to be adjusted; administered as tablets twice daily

Baseline Measures

	Clobazam
Overall Participants [units: participants]	**267**
Age [units: years] Mean (Standard Deviation)	**11.3 (7.80)**
Gender [units: participants]	
Female	**104**
Male	**163**

Outcome Measures

Hide All Outcome Measures

1. Primary: Median Percent Reduction in Average Weekly Rate of Drop Seizures Based on the 7-day Assessment [Time Frame: Baseline to month 36]

Measure Type	Primary
Measure Title	Median Percent Reduction in Average Weekly Rate of Drop Seizures Based on the 7-day Assessment
Measure Description	Number of drop seizures was obtained from seizure diaries
Time Frame	Baseline to month 36
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Clobazam	Start dose was 0.5 mg/kg with a maximum of 40 mg/day to be adjusted; administered as tablets twice daily

Measured Values

	Clobazam
Overall Participants [units: participants]	**113**
Median Percent Reduction in Average Weekly Rate of Drop Seizures Based on the 7-day Assessment [units: percentage of drop seizures] Median (Full Range)	**92.3** **(-588 to 100)**

No statistical analysis provided for Median Percent Reduction in Average Weekly Rate of Drop Seizures Based on the 7-day Assessment

2. Primary: Median Percent Reduction in Average Weekly Rate of Drop Seizures Based on the Last 30-day Assessment [Time Frame: Baseline to month 36]

Measure Type	Primary
Measure Title	Median Percent Reduction in Average Weekly Rate of Drop Seizures Based on the Last 30-day Assessment
Measure Description	Number of drop seizures was obtained from seizure diaries
Time Frame	Baseline to month 36
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Clobazam	Start dose was 0.5 mg/kg with a maximum of 40 mg/day to be adjusted; administered as tablets twice daily

Measured Values

	Clobazam
Overall Participants [units: participants]	**121**
Median Percent Reduction in Average Weekly Rate of Drop Seizures Based on the Last 30-day Assessment [units: percentage of drop seizures] Median (Full Range)	**92.7** **(-752 to 100)**

No statistical analysis provided for Median Percent Reduction in Average Weekly Rate of Drop Seizures Based on the Last 30-day Assessment

3. Secondary: Percent of Patients Considered Treatment Responders Defined as Those With a ≥25%, ≥50%, ≥75%, 100% Reduction in Drop Seizures Based on the 7-day Assessment [Time Frame: Baseline to month 36]

Measure Type	Secondary
Measure Title	Percent of Patients Considered Treatment Responders Defined as Those With a ≥25%, ≥50%, ≥75%, 100% Reduction in Drop Seizures Based on the 7-day Assessment
Measure Description	Number of drop seizures obtained from seizure diaries
Time Frame	Baseline to month 36
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Clobazam	Start dose was 0.5 mg/kg with a maximum of 40 mg/day to be adjusted; administered as tablets twice daily

Measured Values

	Clobazam
Overall Participants [units: participants]	**113**
Percent of Patients Considered Treatment Responders Defined as Those With a ≥25%, ≥50%, ≥75%, 100% Reduction in Drop Seizures Based on the 7-day Assessment [units: percentage of participants]	
Any reduction	**85.8**
≥25% reduction	**82.3**
≥50% reduction	**77.9**
≥75% reduction	**64.6**
100% reduction	**38.1**

No statistical analysis provided for Percent of Patients Considered Treatment Responders Defined as Those With a ≥25%, ≥50%, ≥75%, 100% Reduction in Drop Seizures Based on the 7-day Assessment

4. Secondary: Percent of Patients Considered Treatment Responders Defined as Those With a ≥25%, ≥50%, ≥75%, 100% Reduction in Drop Seizures Based on the Last 30-day Assessment [Time Frame: Baseline to month 36]

Measure Type	Secondary
Measure Title	Percent of Patients Considered Treatment Responders Defined as Those With a ≥25%, ≥50%, ≥75%, 100% Reduction in Drop Seizures Based on the Last 30-day Assessment
Measure Description	Number of drop seizures obtained from seizure diaries
Time Frame	Baseline to month 36
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Clobazam	Start dose was 0.5 mg/kg with a maximum of 40 mg/day to be adjusted; administered as tablets twice daily

Measured Values

	Clobazam
Overall Participants [units: participants]	**121**
Percent of Patients Considered Treatment Responders Defined as Those With a ≥25%, ≥50%, ≥75%, 100% Reduction in Drop Seizures Based on the Last 30-day Assessment [units: percentage of participants]	
Any reduction	**86.0**
≥25% reduction	**83.5**
≥50% reduction	**79.3**
≥75% reduction	**64.5**
100% reduction	**31.4**

No statistical analysis provided for Percent of Patients Considered Treatment Responders Defined as Those With a ≥25%, ≥50%, ≥75%, 100% Reduction in Drop Seizures Based on the Last 30-day Assessment

5. Secondary: Investigator Global Evaluations of the Patient's Overall Change in Symptoms [Time Frame: Baseline to month 36]

Measure Type	Secondary
Measure Title	Investigator Global Evaluations of the Patient's Overall Change in Symptoms
Measure Description	The physician was asked to rate the patient's overall change in symptoms since the beginning of clobazam treatment by checking "very much improved", "much improved", "minimally improved", "no change", "minimally worse", "much worse", or "very much worse".
Time Frame	Baseline to month 36

Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Clobazam	Start dose was 0.5 mg/kg with a maximum of 40 mg/day to be adjusted; administered as tablets twice daily

Measured Values

	Clobazam
Overall Participants [units: participants]	**137**
Investigator Global Evaluations of the Patient's Overall Change in Symptoms [units: percentage of participants]	
VERY MUCH IMPROVED	**35.0**
MUCH IMPROVED	**45.3**
MINIMALLY IMPROVED	**14.6**
NO CHANGE	**2.2**
MINIMALLY WORSE	**0.7**
MUCH WORSE	**1.5**
VERY MUCH WORSE	**0.7**

No statistical analysis provided for Investigator Global Evaluations of the Patient's Overall Change in Symptoms

6. Secondary: Parent/Caregiver Global Evaluations of the Patient's Overall Change in Symptoms [Time Frame: Baseline to month 36]

Measure Type	Secondary
Measure Title	Parent/Caregiver Global Evaluations of the Patient's Overall Change in Symptoms
Measure Description	The parent/caregiver was asked to rate the patient's overall change in symptoms since the beginning of clobazam treatment by checking "very much improved", "much improved", "minimally improved", "no change", "minimally worse", "much worse", or "very much worse".
Time Frame	Baseline to month 36
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Clobazam	Start dose was 0.5 mg/kg with a maximum of 40 mg/day to be adjusted; administered as tablets twice daily

Measured Values

	Clobazam
Overall Participants [units: participants]	**137**
Parent/Caregiver Global Evaluations of the Patient's Overall Change in Symptoms [units: percentage of participants]	
VERY MUCH IMPROVED	**45.3**
MUCH IMPROVED	**35.0**
MINIMALLY IMPROVED	**11.7**
NO CHANGE	**3.6**
MINIMALLY WORSE	**1.5**
MUCH WORSE	**2.9**
VERY MUCH WORSE	**0.0**

No statistical analysis provided for Parent/Caregiver Global Evaluations of the Patient's Overall Change in Symptoms

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	The protocol was written to go up to 60 months treatment however a percentage of patients went beyond 60 months until study completion when commercial product was made available.
Additional Description	No text entered.

Reporting Groups

	Description
Clobazam	Start dose was 0.5 mg/kg with a maximum of 40 mg/day to be adjusted; administered as tablets twice daily

Serious Adverse Events

	Clobazam
Total, serious adverse events	
# participants affected / at risk	**115/267 (43.07%)**
Blood and lymphatic system disorders	
Anaemia † 1	
# participants affected / at risk	**4/267 (1.50%)**
Anaemia Macrocytic † 1	
# participants affected / at risk	**1/267 (0.37%)**
Thrombocytopenia † 1	
# participants affected / at risk	**2/267 (0.75%)**
Cardiac disorders	
Cardio-Respiratory Arrest † 1	
# participants affected / at risk	**1/267 (0.37%)**
Tachycardia † 1	
# participants affected / at risk	**1/267 (0.37%)**

Congenital, familial and genetic disorders	
Hip Dysplasia † 1	
# participants affected / at risk	**1/267 (0.37%)**
Talipes † 1	
# participants affected / at risk	**2/267 (0.75%)**
Endocrine disorders	
Hypothalamo-Pituitary Disorder † 1	
# participants affected / at risk	**1/267 (0.37%)**
Eye disorders	
Eye Disorder † 1	
# participants affected / at risk	**1/267 (0.37%)**
Gastrointestinal disorders	
Barrett's Oesophagus † 1	
# participants affected / at risk	**1/267 (0.37%)**
Constipation † 1	
# participants affected / at risk	**2/267 (0.75%)**
Diarrhoea † 1	
# participants affected / at risk	**1/267 (0.37%)**
Dysphagia † 1	
# participants affected / at risk	**1/267 (0.37%)**
Enterocolitis † 1	
# participants affected / at risk	**1/267 (0.37%)**
Gastritis † 1	
# participants affected / at risk	**2/267 (0.75%)**
Gastrointestinal Perforation † 1	
# participants affected / at risk	**1/267 (0.37%)**
Gastrooesophageal Reflux Disease † 1	
# participants affected / at risk	**1/267 (0.37%)**
Haematemesis † 1	
# participants affected / at risk	**1/267 (0.37%)**
Hiatus Hernia † 1	
# participants affected / at risk	**1/267 (0.37%)**
Ileus † 1	
# participants affected / at risk	**1/267 (0.37%)**
Impaired Gastric Emptying † 1	
# participants affected / at risk	**1/267 (0.37%)**
Intestinal Obstruction † 1	
# participants affected / at risk	**1/267 (0.37%)**
Pancreatic Pseudocyst † 1	
# participants affected / at risk	**1/267 (0.37%)**
Pancreatitis † 1	
# participants affected / at risk	**2/267 (0.75%)**
Pneumoperitoneum † 1	
# participants affected / at risk	**1/267 (0.37%)**
Stomatitis † 1	

# participants affected / at risk	1/267 (0.37%)
Volvulus † 1	
# participants affected / at risk	1/267 (0.37%)
Vomiting † 1	
# participants affected / at risk	5/267 (1.87%)
General disorders	
Death † 1	
# participants affected / at risk	2/267 (0.75%)
Drug Interaction † 1	
# participants affected / at risk	1/267 (0.37%)
Oedema Peripheral † 1	
# participants affected / at risk	1/267 (0.37%)
Pitting Oedema † 1	
# participants affected / at risk	1/267 (0.37%)
Pneumatosis † 1	
# participants affected / at risk	1/267 (0.37%)
Pyrexia † 1	
# participants affected / at risk	5/267 (1.87%)
Hepatobiliary disorders	
Cholecystitis Chronic † 1	
# participants affected / at risk	1/267 (0.37%)
Cholelithiasis † 1	
# participants affected / at risk	2/267 (0.75%)
Infections and infestations	
Bronchopneumonia † 1	
# participants affected / at risk	2/267 (0.75%)
Cellulitis † 1	
# participants affected / at risk	4/267 (1.50%)
Chest Wall Abscess † 1	
# participants affected / at risk	1/267 (0.37%)
Clostridium Difficile Colitis † 1	
# participants affected / at risk	1/267 (0.37%)
Cystitis Klebsiella † 1	
# participants affected / at risk	1/267 (0.37%)
Dengue Fever † 1	
# participants affected / at risk	1/267 (0.37%)
Ear Infection † 1	
# participants affected / at risk	1/267 (0.37%)
Escherichia Urinary Tract Infection † 1	
# participants affected / at risk	1/267 (0.37%)
Febrile Infection † 1	
# participants affected / at risk	1/267 (0.37%)
Fungaemia † 1	
# participants affected / at risk	1/267 (0.37%)
Gastroenteritis † 1	
# participants affected / at risk	4/267 (1.50%)

Gastroenteritis Viral † 1	
# participants affected / at risk	**3/267 (1.12%)**
Implant Site Infection † 1	
# participants affected / at risk	**2/267 (0.75%)**
Incision Site Infection † 1	
# participants affected / at risk	**1/267 (0.37%)**
Influenza † 1	
# participants affected / at risk	**4/267 (1.50%)**
Lobar Pneumonia † 1	
# participants affected / at risk	**5/267 (1.87%)**
Lower Respiratory Tract Infection † 1	
# participants affected / at risk	**1/267 (0.37%)**
Lung Infection Pseudomonal † 1	
# participants affected / at risk	**2/267 (0.75%)**
Oesophageal Candidiasis † 1	
# participants affected / at risk	**1/267 (0.37%)**
Oral Candidiasis † 1	
# participants affected / at risk	**2/267 (0.75%)**
Otitis Media † 1	
# participants affected / at risk	**2/267 (0.75%)**
Periorbital Cellulitis † 1	
# participants affected / at risk	**1/267 (0.37%)**
Peritonsillar Abscess † 1	
# participants affected / at risk	**1/267 (0.37%)**
Pharyngotonsillitis † 1	
# participants affected / at risk	**1/267 (0.37%)**
Pneumonia † 1	
# participants affected / at risk	**26/267 (9.74%)**
Pneumonia Influenzal † 1	
# participants affected / at risk	**1/267 (0.37%)**
Pneumonia Mycoplasmal † 1	
# participants affected / at risk	**1/267 (0.37%)**
Pneumonia Viral † 1	
# participants affected / at risk	**2/267 (0.75%)**
Respiratory Syncytial Virus Bronchiolitis † 1	
# participants affected / at risk	**1/267 (0.37%)**
Respiratory Syncytial Virus Infection † 1	
# participants affected / at risk	**3/267 (1.12%)**
Sepsis † 1	
# participants affected / at risk	**5/267 (1.87%)**
Septic Shock † 1	
# participants affected / at risk	**2/267 (0.75%)**
Sinusitis † 1	
# participants affected / at risk	**1/267 (0.37%)**
Staphylococcal Infection † 1	
# participants affected / at risk	**1/267 (0.37%)**

Tooth Abscess † 1	
# participants affected / at risk	**2/267 (0.75%)**
Tracheitis † 1	
# participants affected / at risk	**2/267 (0.75%)**
Upper Respiratory Tract Infection † 1	
# participants affected / at risk	**2/267 (0.75%)**
Urinary Tract Infection † 1	
# participants affected / at risk	**8/267 (3.00%)**
Urinary Tract Infection Fungal † 1	
# participants affected / at risk	**1/267 (0.37%)**
Varicella † 1	
# participants affected / at risk	**1/267 (0.37%)**
Viral Infection † 1	
# participants affected / at risk	**3/267 (1.12%)**
Viral Tracheitis † 1	
# participants affected / at risk	**2/267 (0.75%)**
Injury, poisoning and procedural complications	
Bloody Airway Discharge † 1	
# participants affected / at risk	**1/267 (0.37%)**
Device Malfunction † 1	
# participants affected / at risk	**1/267 (0.37%)**
Fall † 1	
# participants affected / at risk	**1/267 (0.37%)**
Feeding Tube Complication † 1	
# participants affected / at risk	**2/267 (0.75%)**
Femur Fracture † 1	
# participants affected / at risk	**3/267 (1.12%)**
Foreign Body Trauma † 1	
# participants affected / at risk	**1/267 (0.37%)**
Jaw Fracture † 1	
# participants affected / at risk	**1/267 (0.37%)**
Laceration † 1	
# participants affected / at risk	**2/267 (0.75%)**
Lower Limb Fracture † 1	
# participants affected / at risk	**1/267 (0.37%)**
Shunt Malfunction † 1	
# participants affected / at risk	**2/267 (0.75%)**
Therapeutic Agent Toxicity † 1	
# participants affected / at risk	**5/267 (1.87%)**
Ventriculoperitoneal Shunt Malfunction † 1	
# participants affected / at risk	**1/267 (0.37%)**
Investigations	
Electroencephalogram † 1	
# participants affected / at risk	**2/267 (0.75%)**
Hepatic Enzyme Increased † 1	
# participants affected / at risk	**1/267 (0.37%)**

Oxygen Saturation Decreased † 1	
# participants affected / at risk	**1/267 (0.37%)**
Metabolism and nutrition disorders	
Dehydration † 1	
# participants affected / at risk	**6/267 (2.25%)**
Failure To Thrive † 1	
# participants affected / at risk	**1/267 (0.37%)**
Feeding Disorder † 1	
# participants affected / at risk	**1/267 (0.37%)**
Hyperammonaemia † 1	
# participants affected / at risk	**1/267 (0.37%)**
Hypoalbuminaemia † 1	
# participants affected / at risk	**1/267 (0.37%)**
Hypokalaemia † 1	
# participants affected / at risk	**1/267 (0.37%)**
Hyponatraemia † 1	
# participants affected / at risk	**2/267 (0.75%)**
Hypophagia † 1	
# participants affected / at risk	**1/267 (0.37%)**
Musculoskeletal and connective tissue disorders	
Foot Deformity † 1	
# participants affected / at risk	**1/267 (0.37%)**
Joint Contracture † 1	
# participants affected / at risk	**1/267 (0.37%)**
Mobility Decreased † 1	
# participants affected / at risk	**1/267 (0.37%)**
Muscle Contracture † 1	
# participants affected / at risk	**2/267 (0.75%)**
Muscle Twitching † 1	
# participants affected / at risk	**1/267 (0.37%)**
Scoliosis † 1	
# participants affected / at risk	**5/267 (1.87%)**
Nervous system disorders	
Atonic Seizures † 1	
# participants affected / at risk	**1/267 (0.37%)**
Brain Injury † 1	
# participants affected / at risk	**1/267 (0.37%)**
Complex Partial Seizures † 1	
# participants affected / at risk	**1/267 (0.37%)**
Convulsion † 1	
# participants affected / at risk	**30/267 (11.24%)**
Dystonia † 1	
# participants affected / at risk	**1/267 (0.37%)**
Encephalopathy † 1	
# participants affected / at risk	**2/267 (0.75%)**
† 1	

Epilepsy	
# participants affected / at risk	**2/267 (0.75%)**
Grand Mal Convulsion † 1	
# participants affected / at risk	**4/267 (1.50%)**
Guillain-Barre Syndrome † 1	
# participants affected / at risk	**1/267 (0.37%)**
Hypertonia † 1	
# participants affected / at risk	**1/267 (0.37%)**
Hypotonia † 1	
# participants affected / at risk	**1/267 (0.37%)**
Intracranial Hypotension † 1	
# participants affected / at risk	**1/267 (0.37%)**
Lennox-Gastaut Syndrome † 1	
# participants affected / at risk	**5/267 (1.87%)**
Lethargy † 1	
# participants affected / at risk	**1/267 (0.37%)**
Muscle Spasticity † 1	
# participants affected / at risk	**1/267 (0.37%)**
Myoclonic Epilepsy † 1	
# participants affected / at risk	**1/267 (0.37%)**
Petit Mal Epilepsy † 1	
# participants affected / at risk	**3/267 (1.12%)**
Somnolence † 1	
# participants affected / at risk	**1/267 (0.37%)**
Status Epilepticus † 1	
# participants affected / at risk	**11/267 (4.12%)**
Tremor † 1	
# participants affected / at risk	**1/267 (0.37%)**
Psychiatric disorders	
Abnormal Behaviour † 1	
# participants affected / at risk	**1/267 (0.37%)**
Aggression † 1	
# participants affected / at risk	**1/267 (0.37%)**
Mental Status Changes † 1	
# participants affected / at risk	**1/267 (0.37%)**
Renal and urinary disorders	
Hydronephrosis † 1	
# participants affected / at risk	**1/267 (0.37%)**
Nephrolithiasis † 1	
# participants affected / at risk	**1/267 (0.37%)**
Renal Tubular Necrosis † 1	
# participants affected / at risk	**1/267 (0.37%)**
Trigonitis † 1	
# participants affected / at risk	**1/267 (0.37%)**
Urinary Retention † 1	
# participants affected / at risk	**1/267 (0.37%)**

Reproductive system and breast disorders	
Menorrhagia † 1	
# participants affected / at risk	**1/267 (0.37%)**
Respiratory, thoracic and mediastinal disorders	
Acute Respiratory Distress Syndrome † 1	
# participants affected / at risk	**3/267 (1.12%)**
Adenoidal Hypertrophy † 1	
# participants affected / at risk	**1/267 (0.37%)**
Aspiration † 1	
# participants affected / at risk	**1/267 (0.37%)**
Asthma † 1	
# participants affected / at risk	**1/267 (0.37%)**
Atelectasis † 1	
# participants affected / at risk	**2/267 (0.75%)**
Choking † 1	
# participants affected / at risk	**1/267 (0.37%)**
Cough † 1	
# participants affected / at risk	**1/267 (0.37%)**
Diaphragmatic Hernia † 1	
# participants affected / at risk	**1/267 (0.37%)**
Dyspnoea † 1	
# participants affected / at risk	**1/267 (0.37%)**
Hypoxia † 1	
# participants affected / at risk	**1/267 (0.37%)**
Pleural Effusion † 1	
# participants affected / at risk	**1/267 (0.37%)**
Pneumonia Aspiration † 1	
# participants affected / at risk	**15/267 (5.62%)**
Respiratory Distress † 1	
# participants affected / at risk	**2/267 (0.75%)**
Respiratory Failure † 1	
# participants affected / at risk	**2/267 (0.75%)**
Sleep Apnoea Syndrome † 1	
# participants affected / at risk	**4/267 (1.50%)**
Tonsillar Hypertrophy † 1	
# participants affected / at risk	**2/267 (0.75%)**
Skin and subcutaneous tissue disorders	
Decubitus Ulcer † 1	
# participants affected / at risk	**3/267 (1.12%)**
Swelling Face † 1	
# participants affected / at risk	**1/267 (0.37%)**
Social circumstances	
Activities Of Daily Living Impaired † 1	
# participants affected / at risk	**1/267 (0.37%)**
Surgical and medical procedures	

Brain Operation † 1	
# participants affected / at risk	**1/267 (0.37%)**
Medical Diet † 1	
# participants affected / at risk	**1/267 (0.37%)**
Spinal Operation † 1	
# participants affected / at risk	**1/267 (0.37%)**
Vagal Nerve Stimulator Implantation † 1	
# participants affected / at risk	**4/267 (1.50%)**
Vascular disorders	
Deep Vein Thrombosis † 1	
# participants affected / at risk	**1/267 (0.37%)**
Haematoma † 1	
# participants affected / at risk	**1/267 (0.37%)**
Hypotension † 1	
# participants affected / at risk	**1/267 (0.37%)**
Venous Thrombosis Limb † 1	
# participants affected / at risk	**1/267 (0.37%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (12.0)

Other Adverse Events

Hide Other Adverse Events

Time Frame	The protocol was written to go up to 60 months treatment however a percentage of patients went beyond 60 months until study completion when commercial product was made available.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5

Reporting Groups

	Description
Clobazam	Start dose was 0.5 mg/kg with a maximum of 40 mg/day to be adjusted; administered as tablets twice daily

Other Adverse Events

	Clobazam
Total, other (not including serious) adverse events	
# participants affected / at risk	**241/267 (90.26%)**
Gastrointestinal disorders	
Constipation † 1	
# participants affected / at risk	**35/267 (13.11%)**
Diarrhoea † 1	
# participants affected / at risk	**19/267 (7.12%)**
Vomiting † 1	
# participants affected / at risk	**20/267 (7.49%)**

General disorders	
Fatigue † 1	
# participants affected / at risk	**18/267 (6.74%)**
Pyrexia † 1	
# participants affected / at risk	**48/267 (17.98%)**
Infections and infestations	
Ear Infection † 1	
# participants affected / at risk	**15/267 (5.62%)**
Gastroenteritis † 1	
# participants affected / at risk	**14/267 (5.24%)**
Influenza † 1	
# participants affected / at risk	**17/267 (6.37%)**
Nasopharyngitis † 1	
# participants affected / at risk	**31/267 (11.61%)**
Otitis Media † 1	
# participants affected / at risk	**42/267 (15.73%)**
Pharyngitis Streptococcal † 1	
# participants affected / at risk	**18/267 (6.74%)**
Pneumonia † 1	
# participants affected / at risk	**29/267 (10.86%)**
Sinusitis † 1	
# participants affected / at risk	**32/267 (11.99%)**
Upper Respiratory Tract Infection † 1	
# participants affected / at risk	**75/267 (28.09%)**
Urinary Tract Infection † 1	
# participants affected / at risk	**35/267 (13.11%)**
Viral Infection † 1	
# participants affected / at risk	**29/267 (10.86%)**
Injury, poisoning and procedural complications	
Contusion † 1	
# participants affected / at risk	**21/267 (7.87%)**
Fall † 1	
# participants affected / at risk	**44/267 (16.48%)**
Skin Laceration † 1	
# participants affected / at risk	**24/267 (8.99%)**
Metabolism and nutrition disorders	
Decreased Appetite † 1	
# participants affected / at risk	**14/267 (5.24%)**
Nervous system disorders	
Drooling † 1	
# participants affected / at risk	**22/267 (8.24%)**
Lethargy † 1	
# participants affected / at risk	**26/267 (9.74%)**
Sedation † 1	
# participants affected / at risk	**21/267 (7.87%)**

Somnolence † 1	
# participants affected / at risk	**45/267 (16.85%)**
Psychiatric disorders	
Aggression † 1	
# participants affected / at risk	**22/267 (8.24%)**
Insomnia † 1	
# participants affected / at risk	**31/267 (11.61%)**
Respiratory, thoracic and mediastinal disorders	
Cough † 1	
# participants affected / at risk	**17/267 (6.37%)**
Skin and subcutaneous tissue disorders	
Rash † 1	
# participants affected / at risk	**15/267 (5.62%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (12.0)

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data

No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The agreement is:

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: The sponsor must have the opportunity to review and approve all proposed abstracts, manuscripts, or presentations regarding this study prior to submission for publication/presentation. Any information identified by the Sponsor as confidential must be deleted prior to submission.

Results Point of Contact:

Name/Title: Email contact via H. Lundbeck A/S
Organization: Lundbeck LLC

e-mail: LundbeckClinicalTrials@lundbeck.com

Publications of Results:

Ng YT, Conry J, Paolicchi J, Kernitsky L, Mitchell W, Drummond R, Isojarvi J, Lee D, Owen R; OV-1004 study investigators.. Long-term safety and efficacy of clobazam for Lennox-Gastaut syndrome: interim results of an open-label extension study. Epilepsy Behav. 2012 Dec;25(4):687-94. doi: 10.1016/j.yebeh.2012.09.039.

Ng YT, Conry J, Kernitsky L, Mitchell W, Veidemanis R, Drummond R, Muniz R, Isojarvi J, Lee D, Paolicchi J. Long-Term Safety and Efficacy of Clobazam for Lennox-Gastaut Syndrome: Final Results of an Open-Label Extension Study. Late-Breaking Abstract #1.363 presented at the 66th annual meeting of the American Epilepsy Society, Nov. 30-Dec. 4, 2012, San Diego, California.

Responsible Party:	Lundbeck LLC
ClinicalTrials.gov Identifier:	NCT01160770 History of Changes
Other Study ID Numbers:	**13109A** OV1004 (Other Identifier: Lundbeck LLC ((Formerly Lundbeck Inc. and before that Ovation Pharmaceuticals (OV)))
Study First Received:	June 18, 2010
Results First Received:	February 15, 2013
Last Updated:	March 22, 2013
Health Authority:	Australia: Department of Health and Ageing Therapeutic Goods Administration Belarus: Ministry of Health India: Drugs Controller General of India Lithuania: State Medicine Control Agency - Ministry of Health United States: Food and Drug Administration

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