

# European Registry of Anti-Epileptic Drug Use in Patients with Lennox-Gastaut Syndrome (LGS)

**First published:** 11/12/2013

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS5180

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### Study ID

38601

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### DARWIN EU® study

No

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### Study countries

- ☐ Austria
- ☐ Denmark
- ☐ France
- ☐ Germany

- ☐ Italy
  - ☐ Spain
  - ☐ Sweden
  - ☐ United Kingdom
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### **Study description**

This is a registry study, where sites will enter patients with LGS who require a modification in anti-epileptic therapy (either the addition of another anti-epileptic drug, or the change of one drug to another). This will include patients who are started on rufinamide. Patients will be reviewed according to local practice, but it is envisaged that review will occur at approximately one month, three months and six months, and then every six months. Upon entry to the registry baseline details concerning disease severity, diagnosis, prior therapy, and developmental assessment will be recorded. On each subsequent visit the patient (usually through their caregiver) will be asked about current medication, general seizure profile, any seizures deemed to be of medical significance, tolerability, AEs (including suicidal-related events), and healthcare resource utilisation.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

Eisai

**First published:** 01/02/2024

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**Institution**

Multiple centres: 49 centres are involved in the study

## Contact details

### Study institution contact

Makarand Bagul EUMedInfo@eisai.net

**Study contact**

[EUMedInfo@eisai.net](mailto:EUMedInfo@eisai.net)

### Primary lead investigator

EU Medical Information

**Primary lead investigator**

## Study timelines

### Date when funding contract was signed

Actual: 01/05/2008

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### Study start date

Actual: 30/07/2008

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**Data analysis start date**

Actual: 01/08/2011

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**Date of interim report, if expected**

Planned: 01/12/2013

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**Date of final study report**

Planned: 01/03/2017

Actual: 05/09/2016

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eisai Limited

## Regulatory

**Was the study required by a regulatory body?**

Yes

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**Is the study required by a Risk Management Plan (RMP)?**

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

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**Main study objective:**

Evaluation of safety during the use of rufinamide and other anti-epileptic drugs

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Study drug International non-proprietary name (INN) or common name**

RUFINAMIDE

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**Anatomical Therapeutic Chemical (ATC) code**

(N03A) ANTIEPILEPTICS

ANTIEPILEPTICS

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**Medical condition to be studied**

Lennox-Gastaut syndrome

## Population studied

**Short description of the study population**

Patients (aged  $\geq 4$  years) with Lennox-Gastaut Syndrome (LGS) who required a modification in anti-epileptic therapy (either the addition of another AED or the change of one drug to another); including patients who were already receiving rufinamide.

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**Age groups**

Children (2 to < 12 years)

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

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**Special population of interest**

Other

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**Special population of interest, other**

Lennox-Gastaut Syndrome Patients

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## Estimated number of subjects

225

# Study design details

## Outcomes

Safety during the use of rufinamide and other anti-epileptic drugs: Evaluation of the incidence of seizures of medical significance (including status epilepticus, new / worsening of seizure types and withdrawal seizures) during exposure to anti-epileptic drugs, including rufinamide, in patients with LGS, Long term use of rufinamide, and other anti-epileptic drugs: Evaluation, within the constraints of this population, of the impact on maturation and development that anti-epileptic drugs, including rufinamide, has on the LGS population, seizure control in LGS patients, including those taking rufinamide and other anti-epileptic drugs, assessment of healthcare resource utilisation.

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## Data analysis plan

Seizure profile assessments (including seizures of medical significance, withdrawal seizures, and a generic seizure frequency scale) will be collected at each visit. Seizure data will be summarised using descriptive statistics and graphical displays of longitudinal data. If applicable, longitudinal models or regression models will be used to evaluate changes in seizure variables over time and by subgroups. Safety will be evaluated through the collection of AEs, and detailed information through structured questions on AEs of special interest (including suicidal-related events), and reasons for discontinuation of anti-epileptic drugs. Contrasting of AEs by anti-epileptic drug and combination will be on an ad hoc basis. Incidence rates of AEs will be displayed and Kaplan-Meier plots for key AEs will be presented. Developmental assessment (height and weight) and healthcare resource utilisation will also be performed.

## Documents

## Study results

[Final abstract\\_Rufinamide Study 401-redact - PAS register.pdf](#)(80.45 KB)

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## Data management

### Data sources

#### Data sources (types)

[Disease registry](#)

[Other](#)

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#### Data sources (types), other

Prospective patient-based data collection

### Use of a Common Data Model (CDM)

#### CDM mapping

No

### Data quality specifications

#### Check conformance

Unknown

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#### Check completeness

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## **Data characterisation**

### **Data characterisation conducted**

No