

# A global postmarketing observational safety study to evaluate the safety and tolerability of Fycompa (perampanel) as add-on therapy in epilepsy patients aged > 12 years

**First published:** 17/07/2015

**Last updated:** 05/12/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS10320

---

### Study ID

38590

---

### DARWIN EU® study

No

---

### Study countries

Austria

Denmark

- France
  - Israel
  - Russian Federation
  - Spain
  - Sweden
  - United Kingdom
- 

### **Study description**

The objective of the study is to address the need for additional safety information on AEs of interest in the categories of important identified risks, important potential risks, and important missing information in the EU Risk Management Plan (RMP) for perampanel given as add-on therapy in patients with epilepsy. This will be achieved by assessment of events of dizziness, blurred vision, somnolence, aggression, balance disorders, ataxia, falls, unintended pregnancy, weight gain, suicidality, drug abuse, misuse, dependence, withdrawal, off-label use, skin photosensitivity, unintended pregnancy while taking levonorgestrel-containing contraceptives, and outcomes associated with any suspected drug-drug interaction.

---

### **Study status**

Finalised

## Research institutions and networks

### Institutions

**Eisai**

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

**Last updated:** 01/02/2024

**Institution**

Multiple centres: 100 centres are involved in the study

## Contact details

### **Study institution contact**

Yvonne Lamb [qppv\\_office@eisai.net](mailto:qppv_office@eisai.net)

**Study contact**

[qppv\\_office@eisai.net](mailto:qppv_office@eisai.net)

### **Primary lead investigator**

Yvonne Lamb

**Primary lead investigator**

## Study timelines

### **Date when funding contract was signed**

Planned: 05/12/2012

Actual: 05/12/2012

---

### **Study start date**

Actual: 06/06/2014

---

### **Data analysis start date**

Planned: 30/06/2017

---

### **Date of final study report**

Planned: 31/12/2017

Actual: 24/07/2018

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Eisai Ltd

## Regulatory

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

Yes

---

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition  
Human medicinal product

---

**Study type:**

Non-interventional study

---

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness  
Safety study (incl. comparative)

**Data collection methods:**

Primary data collection

---

**Main study objective:**

Incidence of TEAEs of interest defined as: dizziness, blurred vision, somnolence, aggression, balance disorders, ataxia, falls, unintended pregnancy, weight gain, suicidality, drug abuse, misuse, dependence, withdrawal, off-label use, skin photosensitivity, unintended pregnancy while taking levonorgestrel-containing contraceptives, and outcomes associated with any suspected drug-drug interaction.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

## Medicinal product name

FYCOMPA

---

## Medical condition to be studied

Epilepsy

## Population studied

### Short description of the study population

Subjects who did not meet all of the inclusion criteria or who met any of the exclusion criteria were not eligible to receive treatment.

#### Inclusion Criteria

1. Male or female subjects aged  $\geq 12$  years (or as regionally appropriate) at the time of informed consent
2. Subjects prescribed perampanel for the adjunctive treatment of epilepsy within 7 days of the Screening Visit
3. Subjects who provided informed consent

#### Exclusion Criteria

1. Participation in another study involving administration of an investigational drug or device whilst participating in this observational study
  2. Prior participation in a perampanel clinical study
  3. Hypersensitivity to perampanel
- 

### Age groups

- 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)
- 

### **Special population of interest**

Other

---

### **Special population of interest, other**

Epilepsy patients

---

### **Estimated number of subjects**

500

## Study design details

### **Data analysis plan**

The incidence of TEAEs will be summarized. The incidence of TEAEs of interest, as defined in the primary and secondary variables will be summarized or listed as appropriate. The incidence of SAEs, TEAEs leading to discontinuation, TEAEs by severity, and TEAEs by relationship to treatment will be summarized. HADS scores will be summarized. Change from baseline in weight and the proportion of patients who have at least a 5% and 10% increase in weight from baseline to EOS will be summarized. Duration of treatment and perampanel dose information will be summarized

## Documents

### **Study results**

[e2007-g000-402--study-report-body-redact - PAS register.pdf](#) (319.34 KB)

---

## Data management

## ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

Other

---

### 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

---

### Check completeness

Unknown

---

### Check stability

Unknown

---

**Check logical consistency**

Unknown

**Data characterisation**

**Data characterisation conducted**

No