

# A Multicenter, Multinational, Observational Study to Collect Information on Safety and to Document the Drug Utilization of Fampyra® When Used In Routine Medical Practice (LIBERATE)

**First published:** 29/03/2019

**Last updated:** 14/03/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS28367

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### Study ID

32511

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### DARWIN EU® study

No

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### Study countries

☐ Argentina

☐ Canada

- ☐ Czechia
  - ☐ France
  - ☐ Germany
  - ☐ Ireland
  - ☐ Israel
  - ☐ Lebanon
  - ☐ Netherlands
  - ☐ Norway
  - ☐ Portugal
  - ☐ Spain
  - ☐ United Arab Emirates
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### **Study description**

The primary objective of the study is to collect additional safety data including the incidence rate of seizure and other specific Adverse Events (AEs) of interest from participants taking Fampyra in routine clinical practice. The secondary objectives of this study are to characterize utilization patterns of Fampyra in routine clinical practice, to assess the effectiveness of risk minimization measures as described in the risk management plan for Fampyra, to assess the change over time in participant self-reported evaluation of the physical and psychological impact of Multiple Sclerosis (MS) while taking Fampyra and to assess the change over time in physician assessment of walking ability in participants taking Fampyra (MS participants only).

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

## Biogen

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

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

Institution

Multiple centres: 168 centres are involved in the study

## Contact details

### Study institution contact

Study Director Biogen [ctr@biogen.com](mailto:ctr@biogen.com)

Study contact

[ctr@biogen.com](mailto:ctr@biogen.com)

### Primary lead investigator

Study Director Biogen

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Actual: 07/07/2011

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**Study start date**

Actual: 16/04/2012

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**Date of final study report**

Planned: 08/11/2019

Actual: 05/11/2019

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Biogen

## Study protocol

[218MS401 Protocol V3 FINAL 24Feb14\\_Redacted.pdf](#) (1.32 MB)

## Regulatory

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

No

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

EU RMP category 3 (required)

## Other study registration identification numbers and links

218MS401NCT01480063

<https://clinicaltrials.gov/ct2/show/NCT01480063?term=218ms401&rank=1>

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Disease /health condition

Human medicinal product

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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

**Data collection methods:**

Primary data collection

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**Main study objective:**

The primary objective of the study is to collect additional safety data including the incidence rate of seizure and other specific Adverse Events (AEs) of interest from participants taking Fampyra in routine clinical practice.

### Study Design

## **Non-interventional study design**

Cohort

Other

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## **Non-interventional study design, other**

Prospective, observational study

# Study drug and medical condition

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

FAMPRIDINE

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## **Medical condition to be studied**

Multiple sclerosis

# Population studied

## **Short description of the study population**

To be eligible to participate in this observational study, patients must fulfil the following eligibility criteria at the time of Enrollment:

1. Patients who have been newly prescribed Fampyra according to the terms of the marketing authorization, but who have not yet started treatment with Fampyra.
  2. Patients who are willing and able to provide written informed consent.
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## **Age groups**

- 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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### **Estimated number of subjects**

4734

## Study design details

### **Outcomes**

• Number of Participants with Adverse Events, • Utilization patterns of Fampyra in Routine Clinical Practice • Effectiveness of risk minimization measures • Change from Baseline in Physician's Clinical Global Impression of Improvement (CGI-I) of Walking Ability • Participants' Assessment of Physical and Psychological Impact of Multiple Sclerosis Using the Multiple Sclerosis Impact Scale-29 Items (MSIS-29)

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### **Data analysis plan**

Statistical analyses will be exploratory and descriptive in nature.

## Documents

### **Study results**

[218MS401\\_EUPASResultsPacket\\_Redacted.pdf](#) (288.83 KB)

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## 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

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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