

# Trends in prescriptions of valproate and valpromide for bipolar disorder in IMS France and IMS Germany between 2010 and June 2016 and in UK THIN between 1999 and 2015

**First published:** 18/05/2017

**Last updated:** 15/12/2021

Study

Finalised

## Administrative details

### EU PAS number

EUPAS19162

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### Study ID

44731

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### DARWIN EU® study

No

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### Study countries

 France

 Germany

## Study description

This study will provide drug utilisation data on valproate prescribing among the general population using data from France, Germany and the UK.

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## Study status

Finalised

# Research institutions and networks

## Institutions

### European Medicines Agency (EMA)

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

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

Institution

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Daniel Morales

## Study timelines

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

Planned: 03/01/2017

Actual: 03/01/2017

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### **Study start date**

Planned: 03/01/2017

Actual: 03/01/2017

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### **Data analysis start date**

Planned: 03/01/2017

Actual: 09/01/2017

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

Planned: 31/08/2017

Actual: 06/06/2017

## Sources of funding

- EMA

## Regulatory

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

No

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

Not applicable

## 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:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**Main study objective:**

Measure prevalence and prescribing trends in valproate prescribing overall and in people with certain indications in the general population.

## Study drug and medical condition

## **Anatomical Therapeutic Chemical (ATC) code**

(N03AG01) valproic acid

valproic acid

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## **Medical condition to be studied**

Bipolar disorder

Epilepsy

Migraine

## **Population studied**

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

All patients with a consultation date between 1 January 2010 and 30 June 2016 were identified.

Population denominators used for the analysis of valproate prescribing trends in THIN are defined as follows:

- a) All patients with bipolar disorder meeting cohort entry and exit criteria described above.
- b) All patients in the THIN database.
- c) All patients with a Read code for epilepsy recorded in each calendar year in THIN.
- d) All patients with a Read code for migraine recorded in each calendar year in THIN.

Different cohort denominators were used for epilepsy and migraine to reflect active management of patients as opposed to bipolar disorder which is a more pervasive chronic illness. In this regard, it was noted that inclusion of people simply with a past history of epilepsy and migraine lead to an underestimation of the prevalence of valproate prescribing over time (due to the accrual of non-

active patients).

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### **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)
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### **Special population of interest**

Other

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

Population with Bipolar disorder, Epilepsy and Migraine

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### **Estimated number of subjects**

100000

## Study design details

### **Outcomes**

Prevalence of valproate prescribing overall and in people with certain indications (e.g. bipolar disorder, epilepsy, migraine) in the general population.

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### **Data analysis plan**

Simple descriptive analysis with counts and percentages. Annual and quarterly time trends in valproate prescribing.

## Documents

## Study results

[EMA Valproate\\_prescribing\\_REPORT.pdf](#) (1.19 MB)

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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 source(s)

THIN® (The Health Improvement Network®)

IQVIA Disease Analyzer Germany

Disease Analyzer - OMOP

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### Data sources (types)

[Electronic healthcare records \(EHR\)](#)

## 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