

# Pregabalin abuse in France : a national cohort study

**First published:** 15/07/2015

**Last updated:** 02/07/2024

Study

Finalised

## Administrative details

### EU PAS number

EUPAS10298

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### Study ID

28047

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### DARWIN EU® study

No

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### Study countries

 France

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### Study description

Pregabalin is a psychoactive drug indicated in neuropathic pain, generalized anxiety disorder and partial epilepsy. It modifies neuronal activity, binding  $\alpha 2\delta 1$  presynaptic voltage-dependent calcic channel receptor, which is responsible for

its psychotropic action. Neuropsychiatric adverse drug reactions, such as euphoria, have been described. Pregabalin abuse has been suggested in a few toxicological studies, pharmacovigilance studies, and small surveys among opioid users or treated by opiate maintenance drugs. Despite signals of abuse in some European countries, no data suggest a potential for pregabalin abuse in France, and no study has ever compare pregabalin abuse to other drug used in the same indication. Searching a possible pregabalin abuse seems all the more relevant as its consumption increases in France and in Europe. This study aims to investigate pregabalin abuse and its frequency in the French general population, in comparison with other drugs used in similar indications and to determine the factors associated with pregabalin abuse.

## Study status

Finalised

## Research institutions and networks

### Institutions

Pharmacologie En Population cohorteS biobanqueS (PEPSS), Hopitaux de Toulouse

 France

**First published:** 31/03/2022

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**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

ENCePP partner

## Contact details

### Study institution contact

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Study contact

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### Primary lead investigator

Maryse Lapeyre-Mestre

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 02/02/2015

Actual: 02/02/2015

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### Study start date

Planned: 06/04/2015

Actual: 01/06/2015

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### Data analysis start date

Planned: 04/05/2015

Actual: 15/06/2015

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### Date of final study report

Planned: 30/10/2015

Actual: 24/12/2015

## Sources of funding

- Other

## More details on funding

Toulouse University Hospital

## Study protocol

[Pregabalin study protocol 15\\_07.pdf](#) (666.05 KB)

## 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

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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:**

Secondary use of data

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**Main study objective:**

The main objective of this study will be to assess pregabalin abuse and its frequency in the French general population, in comparison to other drugs with similar indications (gabapentin and duloxetine), in a pharmacoepidemiological, observational, French national retrospective cohort study. The secondary objective is to determine the factors associated with abuse of each drug.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

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

PREGABALIN

GABAPENTIN

DULOXETINE

## Population studied

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

French adult population of both gender, naive of any study medication or medication used in the same indication with abuse potential.

Patients must have the following criteria:

1. Aged 18 or more
  2. New users of pregabalin, gabapentin or duloxetine between the first date of inclusion (15th of June 2006) and until 31th December 2012 (to grant a two-years minimum follow-up),
  3. Subjects being reimbursed at least two delivery of medication group, at different dates (two delivery or more the same day, only once, will be considered as single time user)
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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**

15000

## **Study design details**

### **Outcomes**

Occurrence of drug abuse along time will be the main outcome (abuse of pregabalin in pregabalin group, etc.). The abuse will be defined by the exceeding of maximum daily dose recommended. For every 3 drugs studies,

this maximum corresponds to 2 daily DDD

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### **Data analysis plan**

Outcome will be abuse of the cohort study drug, defined as a daily abuse above the maximum recommended dose. Abuse will be investigated through a Kaplan-Meier survival model. Factors associated with abuse will be investigated through a Cox proportional hazard regression model with time dependent covariates.

## Documents

### **Study results**

[CR\\_CT022015033\\_pharmacodépendance\\_28\\_05\\_2015.pdf](#) (468.24 KB)

[Résumé pregabaline SFPT 2016.pdf](#) (390.82 KB)

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### **Study publications**

[Bossard JB, Ponté C, Dupouy J, Lapeyre-Mestre M, Jouanjus E.](#)

[Disproportionality...](#)

[Driot D, Chicoulaa B, Jouanjus E, Dupouy J, Oustric S, Lapeyre-Mestre M.Pregaba...](#)

[Driot D, Jouanjus E, Oustric S, Dupouy J, Lapeyre-Mestre M. Patterns ofgabapent...](#)

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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.

This study has been awarded the ENCePP seal

### **Conflicts of interest of investigators**

[DOI Pregabalin.pdf](#) (503.42 KB)

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### **Composition of steering group and observers**

[Steering committee.pdf](#) (90.97 KB)

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### **Signed code of conduct**

[Compliance pregabalin.pdf](#) (188.1 KB)

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### **Signed code of conduct checklist**

[Annex2\\_Checklist Code of conduct pregabalin.pdf](#) (1000.96 KB)

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### **Signed checklist for study protocols**

[ENCePPChecklistforStudyProtocols pregabalin.pdf](#) (1.18 MB)

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## Data sources

### **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

[Drug dispensing/prescription data](#)

## 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**

Unknown