

# EMA study on prescribing of ibuprofen in the French primary care setting

**First published:** 28/11/2014

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Study

Finalised

## Administrative details

### EU PAS number

EUPAS8075

### Study ID

14400

### DARWIN EU® study

No

### Study countries

France

### Study description

The present study has been undertaken in the context of the European Medicines Agency's (EMA's) Pharmacovigilance Risk Assessment Committee (PRAC) Article 31 review to evaluate the cardiovascular risks with systemic

ibuprofen medicines. These risks concern high-dose ibuprofen (2,400 mg per day) taken regularly for long periods. Ibuprofen is usually taken at lower doses and for short periods of time. The primary objective of the present analysis is to provide drug utilisation data on the exposure of high-dose ibuprofen prescribing (2,400 mg or above per day) in France in adults. Furthermore, the duration of the prescription will be calculated to estimate the percentage of patients prescribed high-dose ibuprofen for long periods. This analysis includes all patients recorded in the France IMS database as having received a prescription of ibuprofen. The study period includes all data available in IMS France, from 1st January 1997 to 30th June 2014.

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## **Study status**

Finalised

## Research institutions and networks

### Institutions

[European Medicines Agency \(EMA\)](#)

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[Institution](#)

## Contact details

### **Study institution contact**

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**Study contact**

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#### **Primary lead investigator**

Gianmario Candore

**Primary lead investigator**

## Study timelines

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

Planned: 01/11/2014

Actual: 01/11/2014

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#### **Study start date**

Planned: 03/11/2014

Actual: 03/11/2014

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

Planned: 14/11/2014

Actual: 14/11/2014

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## Sources of funding

- Other

## More details on funding

Conducted using EMA resources

## Regulatory

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

Yes

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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:**

Drug utilisation

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**Data collection methods:**

Secondary use of data

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**Main study objective:**

The primary objective of the present analysis is to provide drug utilisation data on the exposure of high-dose ibuprofen prescribing (2,400 mg or above per day) in France in adults. Furthermore, the duration of the prescription will be

calculated to estimate the percentage of patients prescribed high-dose ibuprofen for long periods.

## Study drug and medical condition

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

(M01A) ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS  
ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS

## Population studied

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

Patients recorded in the France IMS database as having received a prescription of ibuprofen from 1st January 1997 to 30th June 2014.

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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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### **Estimated number of subjects**

3889629

## Study design details

## Outcomes

The primary objective of the present analysis is to provide drug utilisation data on the exposure of high-dose ibuprofen prescribing (2,400 mg or above per day) in France in adults. The duration of the prescription will be calculated to estimate the percentage of patients prescribed high-dose ibuprofen for long periods.

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## Data analysis plan

This study is a descriptive analysis of EHR data from IMS Health. No sample size or statistical precision calculation is performed.

## Documents

### Study results

[EMA\\_Ibuprofen IMS \(FR\) report.pdf \(379.77 KB\)](#)

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### Study, other information

[EMA\\_ibuprofen\\_DUS.pdf \(289.75 KB\)](#)

## 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 source(s), other**

IMS Disease Analyser France database

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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

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## Data characterisation

**Data characterisation conducted**

No