

Etude d'impact de la communication menée auprès des médecins prescripteurs d'Epitomax® et ses génériques en France

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Study

Finalised

Administrative details

EU PAS number

EUPAS24731

Study ID

31433

DARWIN EU® study

No

Study countries

 France

Study status

Finalised

Research institutions and networks

Institutions

NA (database study]

Contact details

Study institution contact

Cecile Deal RA-RNDUS-CInclTrlsEU@its.jnj.com

Study contact

RA-RNDUS-CInclTrlsEU@its.jnj.com

Primary lead investigator

Cecile Deal

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 05/05/2017

Actual: 05/05/2017

Study start date

Planned: 31/10/2017

Actual: 31/10/2017

Date of final study report

Planned: 28/12/2017

Actual: 07/02/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Accord Healthcare, Arrow, Biogaran, EG Labo, Janssen, Sandoz, Mylan, Zydus

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Not applicable

If 'other', further details on the scope of the study

Impact assessment of the communication carried out with Epitomax prescribing physicians® and its generics in France

Main study objective:

Comparisons of topiramate prescriptions before and after DHCP letter sent to prescribers. Assessments of indication, patients characteristics, treatment details

Study drug and medical condition

Medicinal product name, other

TOPIRAMATE

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

TOPIRAMATE

Anatomical Therapeutic Chemical (ATC) code

(N03AX11) topiramate

topiramate

Population studied

Short description of the study population

Epitomax prescribing physicians®

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)
-

Estimated number of subjects

4678

Study design details

Outcomes

the impact of the communication plan carried out with physicians in private practice (generalists, psychiatrists, neurologists and paediatricians) involved in the prescription of topiramate-based specialties on the proportion of off-label prescriptions, Describe the situation before & after the communication plan including: how to use topiramate in real conditions of use: profile of patients treated, prescribing methods (dose & duration), demographic characteristics, indication that motivated the prescription of treatment, profile of the prescribers of topiramate-based medicinal products including all the originally-prescribing specialties

Data analysis plan

Cross-sectional, retrospective, observational study of the before/after type conducted using data obtained from panels of prescribers practicing in a non-hospital setting and representative of the national activity.

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

EPPM database: this is a quarterly study on diseases and the prescribing habits of general practitioners and specialists in private practice, in France. LPD (Longitudinal Patient Data) databases: LPD databases collect medical information through observatory physicians who use prescription assistance software to manage their patients and record inform

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