A multicentre, European, observational, Drug Utilisation Study (DUS) of BLI800 (Eziclen®/Izinova®) as a bowel cleansing preparation (DUS (Drug Utilisation Study))

First published: 09/04/2015

Last updated: 02/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/31317

EU PAS number

EUPAS9361

Study ID

31317

DARWIN EU® study

No

Study countries

- [ ] Czechia
- [ ] Germany
- [ ] Netherlands
- [ ] Poland

Study description

The postapproval commitments for BLI800 (Eziclen®/Izinova®) in EU included a request that Ipsen Pharma conducts a DUS to assess drug utilisation in the real life setting in a representative sample of the European target population. The objectives of this DUS are:• Primary objective: to document the misuse of BLI800 (Eziclen®/Izinova®), defined as non-compliance in terms of insufficient liquid intake, during the postapproval period in the real life setting.• Secondary objective: to describe the safety profile of BLI800 (Eziclen®/Izinova®) in routine clinical practice, overall and in case of misuse defined as non-compliance in terms of insufficient liquid intake, and identify any immediate/acute adverse events associated with the use of BLI800 (Eziclen®/Izinova®) in special populations (i.e. the elderly and patients at risk of electrolyte shifts).

Study status

Finalised

Research institutions and networks

Institutions

Ipsen Pharma

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Institution

Multiple centres: 16 centres are involved in the study

Contact details

Study institution contact

Medical Director Primary Care

Study contact

clinical.trials@ipsen.com

Primary lead investigator

Medical Director Primary Care

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/12/2013

Actual: 12/11/2014

Study start date

Planned: 01/10/2015

Actual: 12/10/2015

Data analysis start date

Planned: 03/10/2016

Actual: 04/07/2016

Date of interim report, if expected

Planned: 30/12/2016

Actual: 22/12/2016

Date of final study report

Planned: 31/12/2017

Actual: 02/02/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

IPSEN PHARMA SAS

Study protocol

8-79-58800-001_protocol_redacted_3Oct18.pdf(5.29 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The objective of this study is to assess drug utilisation in the real life setting in a representative sample of the European target population.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multicentre, European, observational

Study drug and medical condition

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

SODIUM SULPHATE

MAGNESIUM SULFATE HEPTAHYDRATE

POTASSIUM SULPHATE

Population studied

Short description of the study population

Patients who were eligible for colon preparation with BLI800 (Eziclen®/Izinova®) and provide written informed consent.

Patients were enrolled from specialised gastroenterology and hepatogastroenterology hospitals/clinics and endoscopy centres and might be inpatients or outpatients.

All patients must fulfil the following criteria:

• They are eligible for a prescription of BLI800 (Eziclen®/Izinova®) as a cleansing bowel preparation in accordance with the marketing authorisation

And

• They sign the ICF.

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)

Special population of interest

Hepatic impaired

Renal impaired

Estimated number of subjects

1285

Study design details

Outcomes

Primary objective is to document the misuse of BLI800 (Eziclen®/Izinova®), defined as non-compliance in terms of insufficient liquid intake, during the postapproval period in the real life setting. Secondary objective is to describe the safety profile of BLI800 (Eziclen®/Izinova®) in routine clinical practice, overall and in case of misuse defined as non-compliance in terms of insufficient liquid intake, and identify any immediate/acute adverse events associated with the use of BLI800 (Eziclen®/Izinova®) in special populations (i.e. the elderly and patients at risk of electrolyte shifts).

Data analysis plan

Sample size is based on the primary endpoint that is to say the proportion of non-compliant patients defined as having taken less than 75% of the prescribed hydration volume (2 L). The sample size for special population should represent

30% of the recruited patients. Assuming a proportion of 50%, this sample size will allow estimating the proportion with a 2- sided 95% level of confidence and a precision of +/- 5%. The total included population will represent 1285 patients.Each site will be required to offer enrolment to consecutive patients requiring bowel cleansing prior to colonoscopy and eligible for BLI800 (Eziclen®/Izinova®) in accordance with the marketing authorisation. All eligible patients at each study centre will be offered enrolment, until 65 patients are enrolled per site. However, the actual numbers will depend on the drug uptake following launch.

Documents

Study results

8-79-58800-001_abstract_redacted_3Oct18.pdf(2.87 MB)

Study publications

Regula J, Spaander M, Suchanek S, Kornowski A, Perrot V, Fischbach W. Sa1982-A ...

Data management

Data sources

Data sources (types)

Other

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

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No