

# 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

### EU PAS number

EUPAS9361

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### Study ID

31317

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### DARWIN EU® study

No

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### Study countries

Czechia

Germany

Netherlands

Poland

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### 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).

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### Study status

Finalised

## Research institutions and networks

### Institutions

**Ipsen Pharma**

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

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**Institution**

Multiple centres: 16 centres are involved in the study

## Contact details

### Study institution contact

Medical Director Primary Care [clinical.trials@ipsen.com](mailto:clinical.trials@ipsen.com)

Study contact

[clinical.trials@ipsen.com](mailto: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

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### Study start date

Planned: 01/10/2015

Actual: 12/10/2015

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### Data analysis start date

Planned: 03/10/2016

Actual: 04/07/2016

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### **Date of interim report, if expected**

Planned: 30/12/2016

Actual: 22/12/2016

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### **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\\_30Oct18.pdf](#) (5.29 MB)

## Regulatory

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

Yes

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

EU RMP category 2 (specific obligation of marketing authorisation)

## Methodological aspects

Study type

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Primary data collection

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**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

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**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

## 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.
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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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### **Special population of interest**

Hepatic impaired

Renal impaired

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### **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).

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## **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\\_30Oct18.pdf](#) (2.87 MB)

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### **Study publications**

## 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](#)

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### 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

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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