A Drug Utilization Study of SEASONIQUE in Europe

First published: 03/01/2019

Last updated: 02/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS25516

Study ID

33794

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ France
- ☐ Italy

Study description

This is an observational retrospective cohort study to characterize drug utilization patterns of SEASONIQUE in European countries. The study population will be identified from an existing European health care databases.

Study status

Finalised

Research institutions and networks

Institutions

IQVIA

United Kingdom

First published: 12/11/2021

Last updated: 22/04/2024

Institution | Non-Pharmaceutical company | ENCePP partner

Contact details

Study institution contact

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Study contact

Niamh.Houston@theramex.com

Primary lead investigator

Houston Niamh

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 28/09/2017

Actual: 28/09/2017

Study start date
Planned: 15/01/2019

Actual: 15/01/2019

Date of final study report
Planned: 30/03/2020

Actual: 13/02/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Theramex UK Ltd

Study protocol

Protocol_FINAL_DR105_WH_50023_DUS.pdf(415.7 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To characterize drug utilization patterns of SEASONIQUE in Europeancountries

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

LEVONORGESTREL

ETHINYLESTRADIOL

Medical condition to be studied

Oral contraception

Population studied

Short description of the study population

Female patients receiving at least 1 prescription for SEASONIQUE during a 3-year time period after product launch in Europe.

Patients were included in the study only if they meet all of the following criteria:

1. female

2. have a record of at least 1 written prescription for SEASONIQUE during the study period

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Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

Estimated number of subjects

100000

Study design details

Data analysis plan

The main analysis will be descriptive and will provide drug utilization of SEASONIQUE use, including duration of use and indication.

Documents

Study results

EU PAS ABSTRACT.pdf(123.6 KB)

Study report

Theramex_Seasonique DUS Report_v 1.0_13 Feb 2020.pdf(1.16 MB)

Study, other information

Change of Sponsor letter DUS.pdf(276.63 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 sources (types)

Administrative healthcare records (e.g., claims)

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