A Drug Utilization Study of SEASONIQUE in Europe

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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



Contact details

Study institution contact

Houston Niamh Niamh. Houston@theramex.com

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 3year 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

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