Drug utilization of Intrarosa (6.5 mg prasterone pessary) in European Countries (ERC-243)

First published: 10/12/2018

Last updated: 15/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS26886

Study ID

49740

DARWIN EU® study

No

Study countries

- ☐ France
- ☐ Spain
- ☐ Sweden

Study description

The overall aim of the DUS is to describe the baseline characteristics and utilization patterns of EU post-menopausal women initiating treatment with Intrarosa.

Study status

Finalised

Research institutions and networks

Institutions

IMS Health

First published: 01/02/2024

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Marlene Montesino

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 20/02/2018

Study start date
Planned: 01/04/2021

Actual: 31/03/2020

Date of interim report, if expected
Actual: 29/03/2022

Date of final study report
Planned: 31/12/2022

Actual: 25/04/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Endoceutics S.A.

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:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

1-Describe the baseline and historical characteristics of female patients initiating Intrarosa. 2-Estimate the proportion of patients that may have been

prescribed Intrarosa outside of the specifications of the product label (‘off-label use’).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

INTRAROSA

Medical condition to be studied

Atrophic vulvovaginitis

Population studied

Short description of the study population

Patients with atrophic vulvovaginitis received treatment with intrarosa (6.5 mg prasterone pessary) in European Countries.

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

Other

Special population of interest, other

Patients with atrophic vulvovaginitis

Estimated number of subjects

1000

Study design details

Data analysis plan

The analyses will be descriptive in nature, performed annually for 3 years, and use counts and percentages for categorical variables and means with standard deviations for continuous variables. Analyses will be performed both for annual and cumulative study periods separately per database and country. Once multiple years of data are available, trends over time will also be reported. In addition, the aggregated number of patients with the correct indication or with pre-existing contraindications as well as potential off-label use will be presented for all countries.

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 source(s)

The Information System for Research in Primary Care (SIDIAP)

Longitudinal Patient Data - France

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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