Observational study on persistent allergic rhinitis patients to evaluate effectiveness of Dymista® nasal spray in daily practice

First published: 19/02/2018

Last updated: 23/04/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS22774

Study ID

23063

DARWIN EU® study

No

Study countries

Austria

Ireland

Sweden

Study description

The objective of this non-interventional study is gathering knowledge on effectiveness of Dymista® nasal spray in routine clinical practice in patients with Persistent Allergic Rhinitis assessed by means of a Visual Analogue Scale (VAS).

Study status

Finalised

Research institutions and networks

Institutions

N/A

Contact details

Study institution contact

Dennis Castor Dennis.Castor@mylan.com

Study contact

Dennis.Castor@mylan.com

Primary lead investigator

N/A N/A

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 30/09/2014

Study start date
Actual: 01/11/2014

Date of final study report
Actual: 16/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

MEDA Pharma GmbH & Co. KG

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To gather knowledge on the effectiveness of Dymista® nasal spray in routine clinical practice in patients with persistent allergic Rhinitis assessed by means of a Visual Analogue Scale (VAS) and sleep quality.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non-interventional study

Study drug and medical condition

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

AZELASTINE HYDROCHLORIDE

FLUTICASONE PROPIONATE

Medical condition to be studied

Rhinitis allergic

Population studied

Short description of the study population

Patients with Persistent Allergic Rhinitis assessed by means of a Visual Analogue Scale (VAS) recieving Dymista® nasal spray in routine clinical practice.

Age groups

- Adolescents (12 to < 18 years)
- 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

Rhinitis allergic patients

Estimated number of subjects

Study design details

Data analysis plan

Descriptive statistics (frequency tables, number, mean, Standard deviation, minimum, 5% percentile, lower quartile, median, upper quartile, 95% percentile, and maximum). Baseline adjusted Analysis of Covariance (ANCOVA) for repeated measurements with factor day for analysis of change over time (exploratory).

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

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

Unknown