Observational Program to Study Prescribing Practices of Montelast, 10 mg Film-coated Tablets (manufactured by Actavis Ltd., Malta for Actavis Group PTC ehf., Iceland) For Treatment of Bronchial Asthma and Allergic Rhinitis

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Study Finalised

Administrative details

EU PAS number

EUPAS13107

Study ID

13108

DARWIN EU® study

No

Study countries

Russian Federation

Study description

The program is a prospective, observational clinical epidemiological study. Acting outpatient department allergologists and pulmonologists are planned to participate in the program. Doctors’ participation is voluntary. No specific procedures different of those used in routine practice are planned (except for data collected in accordance with CRF, to be collected for every subject enrolled). Data collection will be performed at baseline and after treatment completion, but not later than 12 weeks of study. All the procedures and visits schedule are determined by routine clinical practice and are not in any way specified by the protocol. When included into the program, demographic data will be collected, as well as clinical disease manifestations, underlying disease and its treatment, and prescribed treatment with Montelast.

Study status

Finalised

Research institutions and networks

Institutions

Actavis

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Institution

Multiple centres: 50 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ekaterina Mishle

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 25/03/2015

Actual: 25/03/2015

Study start date

Planned: 01/05/2015

Actual: 08/07/2015

Date of final study report

Planned: 20/12/2015

Actual: 15/02/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

LLC Actavis

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

To evaluate tolerability of Montelast in adults’ treatment of bronchial asthma and allergic rhinitis, or combined. To evaluate clinical efficacy of Montelast in adults’ treatment of bronchial asthma and allergic rhinitis, or combined.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prescription event monitoring

Study drug and medical condition

Medicinal product name, other

Montelast

Medical condition to be studied

Asthma

Rhinitis allergic

Population studied

Short description of the study population

Allergologists and pulmonologists prescribing Montelast, 10 mg Film-coated tablets for treatment of bronchial asthma and allergic rhinitis.

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

Asthma patients, Rhinitis allergic patients

Estimated number of subjects

545

Study design details

Data analysis plan

Sample size calculation:Number of subjects for drug registration: As per primary endpoint, it is necessary to specify prognostic factors of BA or AR control achievement in 3 months. Factors will be presented as proportions. Maximal proportions' variability makes nearly 50%. The following formula was used: (Daniel, 1999): n= Z2P(1-P)/ d2 where n = sample size, Z = Z statistics for confidence interval P = expected incidence or proportion d = accuracy Z

statistics (Z): to achieve confidence interval 95% (that is recommended for use), Z = 1.96. CI will make 2d. Sample size of 500 subjects will have the power of n.l.t. 80% to evaluate 50±10% variability factors with two-sided confidence level of 0.05.

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

No