Drug Utilization Study for azilsartan medoxomil in Germany

First published: 03/12/2014

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7998

Study ID

28627

DARWIN EU® study

No

Study countries

Germany

Study description

A retrospective analyses of the IMS Disease Analyzer database to describe prescribing and morbidity patterns in patients prescribed azilsartan medoxomil in Germany.

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Birgit Ehlken

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 31/03/2014

Actual: 31/10/2014

Study start date
Planned: 30/06/2014

Actual: 01/11/2014

Data analysis start date
Planned: 30/06/2014

Actual: 01/11/2014

Date of interim report, if expected
Planned: 31/12/2014

Actual: 01/10/2017

Date of final study report
Planned: 31/12/2018

Actual: 29/10/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

TDC Europe

Study protocol

Azilsmedox-5007 study protocol Drug Utilization Study IMS Germany_Version_13022014 13 May 2014.pdf (336.36 KB)

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:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The primary study objective is to describe the population being prescribed azilsartan medoxomil in terms of demographics (age and gender) and ICD-10 CM based (co-) morbidities.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

EDARBI

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

AZILSARTAN MEDOXOMIL

Medical condition to be studied

Essential hypertension

Population studied

Short description of the study population

All patients (of any age) with at least one prescription for azilsartan medoxomil (ATC code C09CA09) in the reporting period.
Patients who had a record in the database for at least 90 days before the index date were included.

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

Hypertensive patients

Estimated number of subjects

1.156

Study design details

Data analysis plan

Descriptive analysis of prescribing patterns.

Documents

Study results

Azilsmedox-5007 - Summary Results Document.pdf (25.31 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 source(s), other

IMS Lifelink EMS database Germany

Data sources (types)

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

Unknown