

# 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

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### Study ID

28627

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### DARWIN EU® study

No

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### Study countries

Germany

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### Study description

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

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## 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

Paul Dolin [clinicaltrialregistry@tpna.com](mailto:clinicaltrialregistry@tpna.com)

Study contact

[clinicaltrialregistry@tpna.com](mailto:clinicaltrialregistry@tpna.com)

### Primary lead investigator

Birgit Ehlken

Primary lead investigator

## Study timelines

**Date when funding contract was signed**

Planned: 31/03/2014

Actual: 31/10/2014

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**Study start date**

Planned: 30/06/2014

Actual: 01/11/2014

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**Data analysis start date**

Planned: 30/06/2014

Actual: 01/11/2014

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**Date of interim report, if expected**

Planned: 31/12/2014

Actual: 01/10/2017

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**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

## Regulatory

### **Was the study required by a regulatory body?**

No

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### **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

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##### **Study type:**

Non-interventional study

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##### **Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**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

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

AZILSARTAN MEDOXOMIL

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**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.

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### **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)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Hypertensive patients

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### **Estimated number of subjects**

1156

## Study design details

### **Data analysis plan**

Descriptive analysis of prescribing patterns.

## Documents

### **Study results**

## 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

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### **Data sources (types)**

[Electronic healthcare records \(EHR\)](#)

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown