Postmarketing non-interventional safety study on medicinal products containing active substance sildenafil

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Study Planned

Administrative details

EU PAS number

EUPAS11475

Study ID

11476

DARWIN EU® study

No

Study countries

☐ Czechia

Study description

PASS searching and collecting reports on adverse drug reaction, obtaining of information about concomitant therapy, possibility of follow-up of the development of the clinical status of a patient and analyze reports.

Study status

Planned

Research institutions and networks

Institutions

Actavis

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Institution

Contact details

Study institution contact

Eugenia Prochazkova Eugenia.Prochazkova@actavis.com

Study contact

Eugenia.Prochazkova@actavis.com

Primary lead investigator

Martin Pytlik

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 14/04/2014

Study start date
Planned: 16/05/2014

Data analysis start date
Planned: 30/04/2017

Date of final study report
Planned: 28/02/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Actavis

Regulatory

Was the study required by a regulatory body?

No

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Other

If ‘other’, further details on the scope of the study

Patient´s and treatment characteristics

Main study objective:

Obtaining information about safety of the drug and concomitant therapy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

SILDENAFIL

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Estimated number of subjects

1000

Study design details

Data analysis plan

Query investigation with statistical evaluation of results.

Data management

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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