Sildenafil orodispersible film patient-centred experience in the treatment of erectile dysfunction: an observational, prospective, multicentre cohort study (18I-SDF01)

First published: 13/09/2018

Last updated: 31/01/2022

Study Finalised

Administrative details

EU PAS number

EUPAS25496

Study ID

45458

DARWIN EU® study

No

Study countries

☐ Italy

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 17 centres are involved in the study

Contact details

Study institution contact

Valeria Frangione valeria.frangione@ibsa.ch

Study contact

valeria.frangione@ibsa.ch

Primary lead investigator

Vincenzo Mirone

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 17/09/2018

Actual: 12/10/2018

Study start date
Planned: 28/06/2019

Actual: 16/09/2019

Date of final study report
Planned: 30/12/2021

Actual: 13/01/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

IBSA Institut Biochimique

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

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

Prospective observational cohort study

Data collection methods:

Primary data collection

Main study objective:

To gather information on a patient-centred experience with the new formulation of Sildenafil IBSA ODF, and on the new, intermediate 75 mg dose, in the treatment of ED of different origins.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

SILDENAFIL CITRATE

Medical condition to be studied

Erectile dysfunction

Population studied

Short description of the study population

Erectile dysfunction patients.

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)

Estimated number of subjects

525

Study design details

Outcomes

Change from Visit 1 to Visit 3 in the Erectile Function Domain of the 15-item International Index of Erectile Function (IIEF-EF score), effectiveness, patient’s preference, and satisfaction, time to onset of pharmacological effects, treatment safety, patient's evaluation of the ease-of-use

Data analysis plan

Safety Set (SS):data analysis for the safety outcome measures will be performed using data of all enrolled patients for whom evidence of treatment can be documented. Full Analysis Set (FAS): primary and secondary outcome measures will be analysed using data of all enrolled patients. Per Protocol set (PP): a sensitivity analysis using all of the subjects who completed the study.

Data management

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