Safety and efficacy evaluation of Mirvaso gel 0.33 % (brimonidine tartrate) by Post marketing surveillance

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Study Ongoing

Administrative details

EU PAS number

EUPAS17600

Study ID

18044

DARWIN EU® study

No

Study countries

Korea, Republic of

Study status

Ongoing

Research institutions and networks

Institutions

Galderma Korea

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Fabien Audibert

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/09/2016

Actual: 15/09/2016

Study start date

Planned: 15/12/2016

Actual: 15/12/2016

Data analysis start date
Planned: 15/09/2017

Date of interim report, if expected
Planned: 15/11/2017

Date of final study report
Planned: 15/11/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Galderma Korea Ltd

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

This Post Marketing Study (PMS) aims to evaluate follow items after launching Mirvaso gel 0.33% (brimonidiine tartrate) in general medical circumstances. 1) Serious adverse events adverse drug reactions2) Unlabelled, unexpected adverse events, adverse drug reactions3) Known adverse drug reactions4) Non-serious adverse drug reactions5) Other safety, efficacy related information

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Non interventional study aiming at collecting supplementary safety data on Mirvaso under real life medical practice

Study drug and medical condition

Medicinal product name

MIRVASO

Medical condition to be studied

Rosacea

Population studied

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

600

Study design details

Outcomes

AE/SAE: number of occurrence case, occurrence rate with 95% confidence interval, Efficacy as assesed by CEA and PSA

Data analysis plan

AE or SAE will be analysed the number of occurrence case, and occurrence rate with 95% confidence interval

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