Post marketing surveillance to evaluate Soolantra cream 1% for the treatment of inflammatory lesions of rosacea in adult patients

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Study Planned

Administrative details

EU PAS number

EUPAS22329

Study ID

22330

DARWIN EU® study

No

Study countries

☐ Korea, Republic of

Study status

Planned

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: 31/08/2017

Actual: 31/08/2017

Study start date

Planned: 15/12/2017

Data analysis start date
Planned: 31/07/2018

Date of interim report, if expected
Planned: 22/10/2018

Date of final study report
Planned: 22/10/2020

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:

Drug utilisation

Main study objective:

This Post Marketing Surveillance (PMS) aims to evaluate the safety and efficacy of Soolantra cream 1% in adult patients in practical usage condition.(1) Serious adverse events adverse drug reactions(2) Serious or non-serious unlisted, unexpected adverse events or adverse drug reactions(3) Listed serious or non-serious adverse drug reactions (4) Other safety, efficacy related information

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine, other

Soolantra cream 1% (Ivermectin)

Medical condition to be studied

Papulopustular 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

The number of occurrence case, occurrence rate and frequency of AE, SAE, ADR, SADR, unexpected AE, unexpected SAE, unexpected ADR and unexpected SADR will be analyzed with Wald or 95% confidence interval, Absolute change and change rate in inflammatory lesion count from baseline at 4 weeks after administrationOverall improvement rate at 4 weeks after administration

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Data analysis plan

number of occurrence case, occurrence rate and frequency of AE, SAE, ADR, SADR, unexpected AE, unexpected SAE, unexpected ADR and unexpected SADR will be analyzed with Wald or 95% confidence interval

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