An Observational Post-Authorisation Safety Study of Skilarence in European Psoriasis Registers

First published: 25/02/2019

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Study Ongoing

Administrative details

EU PAS number

EUPAS28457

Study ID

36212

DARWIN EU® study

No

Study countries

- [ ] Germany
- [ ] Ireland
- [ ] Spain
- [ ] United Kingdom

Study description

Psoriasis is a chronic inflammatory skin disorder that results from complex interactions between genes, the immune system, and environmental factors, although the exact cause remains unclear. Skilarence (dimethyl fumarate, DMF) received European marketing authorisation for the treatment of moderate to severe chronic plaque psoriasis in adult patients on 23 June 2017.This study aims to evaluate the long-term safety of Skilarence used for the treatment of patients with moderate to severe psoriasis. The study will evaluate whether the use of Skilarence is associated with an increased risk of serious infections (including serious opportunistic infections such as progressive multifocal leukoencephalopathy), malignancies, or renal impairment as compared with conventional (non-biologic) systemic therapies. In addition, the study aims to describe the use of Skilarence in patient subgroups for which there is missing information. The study is a long-term, non-interventional, observational post-authorisation safety study that will use a prospective cohort design, and data from established registers of patients with psoriasis treated with systemic therapies in Germany, Spain, and the UK and Ireland.

Study status

Ongoing

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- ☐ France
- ☐ Spain

- [ ] Sweden
- [ ] United Kingdom
- [ ] United Kingdom (Northern Ireland)
- [ ] United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

University Medical Centre Hamburg-Eppendorf

- [ ] Germany

First published: 01/02/2024

Last updated: 01/02/2024

Institution | Educational Institution | Hospital/Clinic/Other health care facility

Fundación Academia Española de Dermatologia y Venereología

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Fundación de la Academia Española de Dermatología y Venereología Madrid, Spain, University Medical Center Hambug-Eppendorf (UKE) Hamburg, Germany, British Association of Dermatologists Biologics Register Limited (BADBIR) Manchester, United Kingdom

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Elena Rivero

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 30/09/2018

Actual: 17/12/2018

Study start date
Planned: 29/03/2019

Actual: 14/05/2019

Data analysis start date
Planned: 01/04/2027

Date of final study report
Planned: 31/03/2028

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Almirall S.A.

Study protocol

0304446_Skilarence PASS Protocol_Final_14Jun2018_signatures redacted.pdf
(864.18 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

The primary objectives are to evaluate the risk of serious infections, malignancies, and renal impairment in new users of Skilarence compared with new users of conventional systemic therapies and to describe the characteristics of users of Skilarence and users of conventitional systemic therapies.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

SKILARENCE

Medical condition to be studied

Psoriasis

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

1600

Study design details

Outcomes

- All serious infections- Serious opportunistic infections (including progressive multifocal leukoencephalopathy)- All malignancies- All renal impairments, including Fanconi syndrome, - All “other” SAEs by MedDRA System Organ Class- All AEs by MedDRA System Organ Class

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Data analysis plan

Annual analyses based on standard periodic analyses conducted by each register, describing:-Cohorts at baseline using mean values and standard deviations for continuous variables and percentages for categorical variables-Treatment course, including number of patients and cumulative person-time in each cohort, proportion of treatment discontinuations and reasons for discontinuation -Safety endpoints-All “other” SAEs and AEsFinal analyses, at end of study period:-Incidence rates for patients initiating Skilarence and for patients initiating other conventional systemic therapies will be estimated overall and stratified by relevant baseline factors -Crude, stratified, and adjusted incidence rates ratio estimates comparing Skilarence and other

conventional systemic therapies -Point estimates from pooled analysis of estimates from the three registers: incidence rates, overall and stratified by selected factors, and IRRs adjusted for relevant factors

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

Exposure registry

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