

# Retrospective chart review to assess the effectiveness of the Skilarence® risk minimisation activities in daily practice – a post-authorisation safety study (PASS) (RETROSKIL)

**First published:** 23/12/2019

**Last updated:** 20/09/2023

Study

Finalised

## Administrative details

### EU PAS number

EUPAS29842

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### Study ID

37187

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### DARWIN EU® study

No

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### Study countries

 Germany

 United Kingdom

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## Study description

The aim of this PASS is to assess the effectiveness of risk minimisation measures for Skilarence® in daily clinical practice. The Summary of Product Characteristics (SmPC) and an educational programme aim to inform health care professionals about the risk of serious opportunistic infections such as progressive multifocal leukoencephalopathy (PML), associated with the use of Skilarence® and to provide guidance on how to minimise and manage this risk through appropriate monitoring of lymphocyte and leukocyte count abnormalities.

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## Study status

Finalised

## Contact details

### Study institution contact

Miriam Zanuy Porquet [dsafety@almirall.com](mailto:dsafety@almirall.com)

Study contact

[dsafety@almirall.com](mailto:dsafety@almirall.com)

### Primary lead investigator

Faber Susanne

Primary lead investigator

## Study timelines

### Date when funding contract was signed

Planned: 15/06/2018

Actual: 15/06/2018

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### **Study start date**

Planned: 30/06/2019

Actual: 23/03/2021

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### **Data analysis start date**

Actual: 23/12/2021

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### **Date of final study report**

Planned: 31/12/2020

Actual: 15/12/2022

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Almirall S.A

## Regulatory

### **Was the study required by a regulatory body?**

Yes

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

EU RMP category 3 (required)

## Methodological aspects

### Study type

### Study type list

**Study topic:**

Human medicinal product

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Main study objective:**

To assess the effectiveness of risk minimisation measures for Skilarence® in daily clinical practice. The Summary of Product Characteristics (SmPC) and an educational programme aim to inform HCPs about the risk of serious opportunistic infections such as PML, associated with the use of Skilarence® and to provide guidance on how to minimise and manage this risk through appropriate monitoring of lym

## Study Design

**Non-interventional study design**

Other

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**Non-interventional study design, other**

Retrospective Chart Review (RCR)

## Study drug and medical condition

## Medicinal product name

SKILARENCE

# Population studied

## Short description of the study population

The study population included patients treated with Skilarence® under routine clinical practice.

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## 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)
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## Estimated number of subjects

173

# Study design details

## Outcomes

Number of patients who adhere to the appropriate monitoring of lymphocyte and leukocyte counts and who comply with the associated actions to be taken with regard to Skilarence® treatment as described in the SmPC and as detailed in the educational material. Patient characteristics of interest: Demographics (age, sex), BMI, smoking status, alcohol use, Baseline comorbidities, Comedications at baseline Disease characteristics. Average starting dose and

average maintenance dose of Skilarence® based on physicians' prescriptions  
Number of patients with recorded diagnosis of serious infections  
Number of patients with ADRs and SADR

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### **Data analysis plan**

All analyses are exploratory and descriptive in nature and will be performed using epidemiological methods as appropriate. Categorical variables will be analysed by frequency tables (absolute and relative frequencies) and continuous variables by summary statistics (mean, standard deviation, median, minimum, maximum, and quartiles). For categorical variables changes from baseline will be presented in shift tables. Due to the nature of the data sources and the non-interventional approach, missing and inconsistent data will occur and will be considered in the analysis and the assessment of the results. All analyses will be performed overall and for each country separately. Depending on scientific interest and the distribution of the data, subsequent exploratory analyses may be performed.

## 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)**

Electronic healthcare records (EHR)

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

### **Check conformance**

Unknown

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No