ENSTILAR RWE STUDY, IN FRENCH EMR DATABASE (THIN®)

First published: 16/01/2023

Last updated: 30/01/2025

Study Finalised

Administrative details

EU PAS number

EUPAS50585

Study ID

50586

DARWIN EU® study

No

Study countries

☐ France

Study description

The research aim of this project is to better understand the utilization of Enstilar®, compared to Daivobet®, according to patient profile and treatment pathway and outcomes. A second objective is to characterize the Enstilar®

prescription for “beyond mild” patients in France. This translates into a primary objective being to describe and compare profiles of patients who received Enstilar® and/or Daivobet®. The secondary objective is to describe, through a follow-up period, the treatment pathway and health resource utilization (HRU) for patients prescribed Enstilar® compared to Daivobet®. The research aim of this project is to better understand the utilization of Enstilar®, compared to Daivobet®, according to patient profile and treatment pathway and outcomes. A second objective is to characterize the Enstilar® prescription for “beyond mild” patients in France. This translates into a primary objective being to describe and compare profiles of patients who received Enstilar® and/or Daivobet®. The secondary objective is to describe, through a follow-up period, the treatment pathway and health resource utilization (HRU) for patients prescribed Enstilar® compared to Daivobet®.

Study status

Finalised

Research institutions and networks

Institutions

Cegedim Health Data (CHD)

France

First published: 01/02/2024

Last updated: 01/02/2024

Institution **Other** **ENCePP partner**

Contact details

Study institution contact

Delphine PERTUS deprr@leo-pharma.com

Study contact

deprr@leo-pharma.com

Primary lead investigator

Caroline Eteve

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 24/11/2021

Study start date

Actual: 30/05/2022

Data analysis start date

Actual: 04/07/2022

Date of final study report

Actual: 13/01/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

LEO Pharma

Study protocol

Leo_Cegedim_Enstilar RWE protocol_Final may 2022.pdf(1.76 MB)

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:

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The research aim of this study is to better understand the utilization of Enstilar®, compared to Daivobet®, according to patient profile, treatment pathway, and evolution and to characterize the Enstilar® prescription for “beyond-mild” patients in France.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, longitudinal, multicentric, retrospective and prospective study

Study drug and medical condition

Name of medicine, other

ENSTILAR

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

CALCIPOTRIOL

BETAMETHASONE

Medical condition to be studied

Psoriasis

Population studied

Short description of the study population

The study population included patients aged 18 years or older diagnosed with psoriasis received treatment with Enstilar® and/or Daivobet® between April 1, 2018 and May 31, 2022 identified through the THIN® France database.

Inclusion criteria:

1. Patient aged 18 years or more
2. Followed by a panelist physician, GPs or Dermatologists, from the THIN® France database
3. With at least one record of psoriasis diagnosis in their electronic file (ICD10 : L40.0, L40.1, L40.3, L40.8, L40.9)
4. Who received Enstilar® and/or Daivobet® between April 1, 2018 and May 31, 2022

Exclusion criteria:

1. Patients with consultation history less than 3 months prior to inclusion
2. Patients without history reimbursement integrated (HRi) between the 75th and the 105th days before inclusion
3. Patients without any consultation at 3 months or more after inclusion

For the follow-up cohorts:

4. Patients without complete reimbursement history during the 18 months of

follow-up

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)

Special population of interest

Other

Special population of interest, other

Patients with psoriasis

Estimated number of subjects

8414

Study design details

Outcomes

understand the utilization of Enstilar®, compared to Daivobet®, according to patient profile and treatment pathway and outcomes., - to describe through an 18 month follow-up treatment pathway and HRU for patients prescribed with Enstilar® compared to Daivobet®. - to characterize profile of patients with “beyond-mild” psoriasis and under Enstilar®, to assess how they are prescribed with Enstilar® and to describe their follow-up - to better describe psoriasis severity and its impact on quality of life

Data analysis plan

Patients’ characteristics (including demographic characteristics, comorbidities and concomitant treatment) at inclusion will be compared between patients being under Enstilar® versus Daivobet®. Summary statistics (mean, median, SD, quartile, 3rd quartile, range for continuous variables and number of patients and percentages) will be calculated overall and per treatment group. Univariate comparisons will be performed using Chi-square (or Fisher) test and Student (or Wilcoxon) test as appropriate according to the class of the variable of interest. Follow-up cohort: descriptive analyses of HRU and treatment patterns will be carried out in the two groups (Enstilar® versus Daivobet®). Second, time to switch to other psoriasis treatment in the two groups will be described using Kaplan Meier curve and compared using propensity score method to adjust on differences observed at baseline (delivery of Enstilar® of Daivobet®).

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Data sources (types)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

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