DARWIN EU® – Drug Utilisation Study of terbinafine-containing products

First published: 23/10/2025

Last updated: 20/08/2026

Study Finalised

Administrative details

EU PAS number

EUPAS1000000790

Study ID

1000000790

DARWIN EU® study

Yes

Study countries

- Croatia
- Denmark
- Finland
- Germany
- Spain
- United Kingdom

Study description

Terbinafine is an antifungal agent indicated for the treatment of superficial mycoses, with widespread use across Europe in both oral and topical formulations. Monitoring its utilisation is essential to informing regulatory decision-making, particularly in relation to emerging safety concerns, such as antifungal resistance. This study aims to characterise the incidence and patterns of terbinafine use, describe the clinical profiles of treated patients, and examine treatment pathways.

Study status

Finalised

Research institutions and networks

Institutions

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands

First published: 03/11/2022

Last updated: 02/05/2024

Institution **Educational Institution** **ENCePP partner**

Networks

Data Analysis and Real World Interrogation Network (DARWIN EU®)

- Belgium
- Croatia
- Denmark
- Estonia
- Finland
- France
- Germany
- Greece
- Hungary
- Italy
- Netherlands
- Norway
- Portugal
- Spain
- Sweden
- United Kingdom

First published: 01/02/2024

Last updated: 30/04/2025

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Ellen Gerritsen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 14/07/2025

Actual: 14/07/2025

Study start date

Planned: 06/10/2025

Actual: 06/10/2025

Date of final study report

Planned: 30/01/2026

Actual: 05/12/2025

Sources of funding

- EMA

Study protocol

DARWIN EU_Protocol_P4-C1-018_DUS Terbinafine_V2.0.pdf (952.07 KB)

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 topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Study design:

A retrospective cohort study will be conducted using routinely collected health data from 7 data sources from 6 countries across Europe and in 5 EU member states.

Main study objective:

1. To calculate the monthly and annual incidence of terbinafine use, overall and stratified by age and sex.
2. To characterise patients at the time of terbinafine treatment initiation in terms of i) demographics, ii) indication for use, iii) comorbidities, iv) antifungal and antibiotic treatments (6, 3, and 1 month prior to treatment initiation and 6 months following initiation for antifungal treatment), and v) disease code for resistance (6 months before and 6 months after treatment initiation).
3. To report the number of treatment initiations, dose (initial, cumulative), and duration of terbinafine use, overall and stratified by type of dermatophytosis.
4. To explore the treatment pattern following each terbinafine treatment initiation, overall and by type of dermatophytosis, including transitions between topical to systemic and combination therapies.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name, other

Terbinafine

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

TERBINAFINE

Anatomical Therapeutic Chemical (ATC) code

(D01AE15) terbinafine

terbinafine

(D01BA02) terbinafine

terbinafine

Medical condition to be studied

Dermatophytosis

Fungal infection

Population studied

Short description of the study population

For calculation of incidence rates of terbinafine-containing product use, the study population will include the general population (objective 1).

Inclusion criteria:

• All individuals present in the data source between 1 January 2015 and 31 December 2024 (or latest available date).

• At least 1 year of data visibility prior to the index date.

Exclusion criteria:

• Children aged <1 year at any time during the study period.

For characterisation of terbinafine treatment initiators (objectives 2), estimation of treatment utilisation (objective 3), and description of treatment patterns (objective 4), the study population will include individuals with a first recorded prescription of a terbinafine-containing product prescription during the study period.

Inclusion criteria:

• First record of a terbinafine-containing product between 1 January 2015 and 31 December 2024 (or latest available date).

• At least 1 year of data visibility prior to the index date.

• No use of terbinafine products in previous 180 days.

Exclusion criteria:

• Children aged <1 year at the index date.

• Individuals initiating terbinafine treatment <1 year before the end of data availability in the respective data source (to ensure sufficient follow-up).

Additionally, for estimation of treatment utilisation (objective 3), multiple treatment episodes will be considered.

Inclusion criteria:

• New record of a terbinafine-containing product between 1 January 2015 and 31 December 2024 (or latest available date).

• At least 1 year of data visibility prior to the index date.

• No use of terbinafine products 180 days before each treatment episode.

Exclusion criteria:

• Children aged <1 year at the index date.

• Individuals initiating terbinafine treatment <1 year before the end of data availability in the respective data source (to ensure sufficient follow-up).

Age groups

- **In utero**
- **Paediatric Population (< 18 years)**
  - Neonate
    - Preterm newborn infants (0 – 27 days)
    - Term newborn infants (0 – 27 days)
  - Infants and toddlers (28 days – 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)

- **Adult and elderly population (≥18 years)**
  - Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly (≥ 65 years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)

Study design details

Setting

This study was conducted using routinely collected data from 3 registries and 3 primary care data sources in the DARWIN EU® network of data partners from 6 European countries in 5 EU member states.

Outcomes

The outcomes were as follows:

• Incidence rate of terbinafine use (objective 1)

• Characterisation of terbinafine initiators (objective 2)

• Initial and cumulative dose, and duration of first terbinafine treatment initiation (objective 3)

• Number of treatment initiations, initial and cumulative dose, and duration of all terbinafine treatment initiations (objective 3)

• Treatment patterns following first terbinafine treatment initiation during the study period (objective 4)

Summary results

CONCLUSION

This multi-country study provides comprehensive real-world evidence on terbinafine use across six European healthcare systems. Incidence rates were stable over time, with clear seasonal peaks reflecting the epidemiology of dermatophyte infections and a transient decline in 2020 likely associated with the COVID-19 pandemic. Treatment patterns generally aligned with clinical guidelines, with topical terbinafine used for superficial infections and systemic therapy for onychomycosis. Median treatment durations and doses were broadly consistent with recommended regimens, although variability across data sources suggested differences in prescribing practices, product availability, and data capture rather than true divergence in clinical care.
A substantial proportion of patients continued with additional antifungal treatment after terbinafine initiation, reflecting the heterogeneous and often stepwise management of dermatophyte infections in routine practice. Although each individual treatment pathway occurred at low frequency, their overall presence underscores the diversity of real-world clinical decision-making and possibly the need for individualised treatment in certain cases. No coded evidence of terbinafine resistance was identified; however, resistance may not be routinely documented as a clinical code and is often managed through therapeutic adjustments rather than diagnostic coding. Overall, these findings provide robust real-world evidence to inform regulatory assessment of terbinafine use in Europe.

Documents

Study report

DARWIN EU_Report_P4-C1-018_DUS Terbinafine_V3.pdf (4.41 MB)

Shiny App

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 source(s)

Croatia National Public Health Information System (Nacionalni javnozdravstveni informacijski sustav)

Danish Health Data Registries

Hospital District of Helsinki and Uusimaa patient cohort (FinOMOP)

IQVIA Disease Analyzer Germany

BIFAP - Base de Datos para la Investigación Farmacoepidemiológica en el Ámbito Público (Pharmacoepidemiological Research Database for Public Health Systems)

The Information System for Research in Primary Care (SIDIAP)

Clinical Practice Research Datalink (CPRD) GOLD

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

CDM version

https://ohdsi.github.io/CommonDataModel/index.html

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No