

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

**First published:** 23/10/2025

**Last updated:** 30/01/2026

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000790

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### Study ID

1000000790

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### DARWIN EU® study

Yes

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### Study countries

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

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## 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

Natasha Yefimenko study@darwin-eu.org

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

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**Study start date**

Planned: 06/10/2025

Actual: 06/10/2025

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**Date of final study report**

Planned: 30/01/2026

Actual: 05/12/2025

## Sources of funding

- EMA

## Study protocol

## Regulatory

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

Yes

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

Not applicable

## 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:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**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

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

TERBINAFINE

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### **Anatomical Therapeutic Chemical (ATC) code**

(D01AE15) terbinafine

terbinafine

(D01BA02) terbinafine

terbinafine

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### **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).

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## **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 ( $\geq 18$  years)**

- Adults (18 to < 65 years)
  - Adults (18 to < 46 years)
  - Adults (46 to < 65 years)
- Elderly ( $\geq 65$  years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)

## 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

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#### **CDM website**

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

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#### **CDM version**

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

## 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