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

First published: 23/10/2025

Last updated: 23/10/2025





Administrative details

EU PAS number
EUPAS100000790
Study ID
100000790
DARWIN EU® study
'es
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

Ongoing

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

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

study@darwin-eu.org

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

Sources of funding

• EMA

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

Study design:

Data collection methods:

Secondary use of data

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

Name of medicine, other

Terbinafine

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

TERBINAFINE

Anatomical Therapeutic Chemical (ATC) code

(D01AE15) terbinafine

terbinafine
(D01BA02) terbinafine
terbinafine

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

ΑII

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)

Data management

ENIC - DD C - - I

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

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