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

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BACKGROUND

Terbinafine is an antifungal drug indicated for the treatment of superficial mycoses, available in both oral and topical formulations.[1,2] Real-world evidence on its utilisation is essential for monitoring prescribing practices, clinical characteristics, and potential safety concerns, including antifungal resistance.[3]

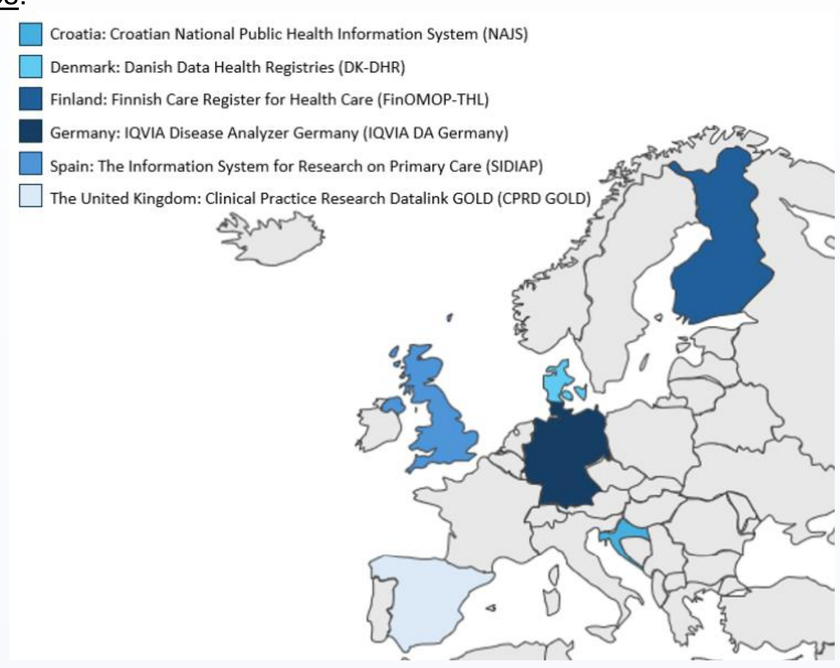
OBJECTIVES

This study aimed to describe the incidence and patterns of terbinafine use, characterise the clinical profiles of patients receiving the medication, and explore treatment pathways across Europe.

MATERIALS AND METHODS

Study design: A retrospective cohort study.

Data sources:



All data sources previously mapped their data to the OMOP Common Data Model (CDM).

Study population: For incidence analyses, the study population included all individuals present in the data source during the study period and with at least one year of data visibility prior to the index date. For characterisation, drug utilisation, and treatment patterns, the study population included individuals with a first recorded prescription of a terbinafine-containing product during the study period, with at least one year of data visibility prior to treatment initiation and no recorded use in the 180 days preceding treatment initiation.

Study period: 2015 – 2024.

Drugs of interest: Terbinafine for topical use and for systemic use.

Conditions of interest: Dermatophytosis (Tinea infections), such as Tinea corporis (Ringworm of the body), Tinea cruris, Tinea pedis (Athlete's foot), Tinea manuum, Tinea capitis, Tinea barbae, and Tinea unguium (Onychomycosis (nail)), and other fungal infections, such as Cutaneous candidiasis, Sporotrichosis, and Pityriasis versicolor.

Data analysis: Monthly and annual incidence rates of terbinafine use were estimated as treatment initiations per 1,000 person-years among eligible individuals, overall and stratified by age and sex. The analyses were based on OMOP CDM mapped data using the *IncidencePrevalence* R package. Characteristics of terbinafine initiators and drug utilisation were assessed using *CohortCharacteristics* and *DrugUtilisation* R packages on OMOP CDM mapped data. The treatment pattern following the first recorded terbinafine prescription was visualised by Sunburst plots, stratified by type of dermatophytosis, using the *TreatmentPatterns* R package.

RESULTS

Across six European data sources, 1,230,556 individuals initiated terbinafine treatment between 2015 and 2024. Monthly and annual incidence rates ranged from approximately 1 to over 10 initiations per 1,000 person-years, with clear seasonal peaks during warmer months and a transient decline in 2020, likely reflecting the COVID-19 pandemic (**Figure 1, Figure 2**). Incidence was highest in Nordic sources (FinOMOP-THL and DK-DHR), followed by NAJS, SIDIAP, and CPRD GOLD, and lowest in IQVIA DA Germany (**Figure 1, Figure 2**). Older adults (≥66 years) consistently exhibited the highest incidence rates, followed by adults aged 19–65 years and children/adolescents. Males generally had higher incidence than females, except in NAJS, where females predominated.

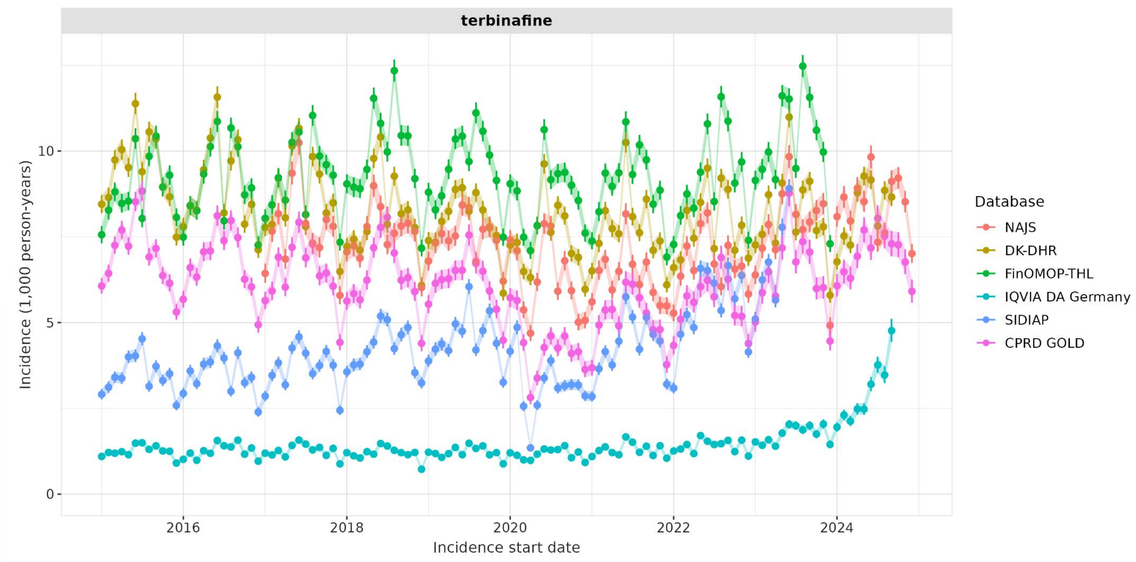


Figure 1. Monthly incidence of terbinafine use across six European data sources (2015–2024).

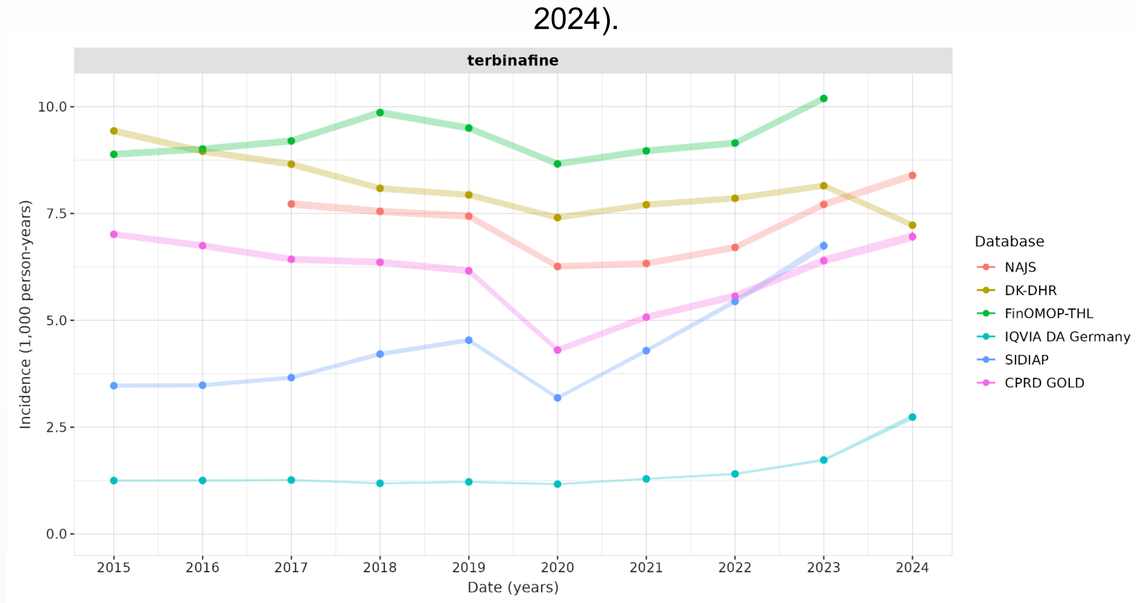


Figure 2. Annual incidence of terbinafine use across six European data sources (2015–2024).

Among terbinafine initiators, the median age ranged from 47 to 57 years, with adults representing the majority and older adults accounting for up to 31%. Dermatophytosis was the most frequently recorded indication, particularly onychomycosis, although the proportion of other indication codes varied substantially across sources. Comorbidity profiles at the time of initiation were dominated by fungal and dermatological conditions, with chronic conditions such as hypertension and diabetes also common, especially in older adults. Treatment patterns showed that most patients initiated terbinafine as monotherapy, with topical formulations for superficial tinea infections and systemic therapy for onychomycosis. Sequential switching was observed in a substantial proportion of individuals, typically involving transitions to other topical or systemic antifungal agents. No coded evidence of terbinafine resistance was identified during the study period.

CONCLUSIONS

Incidence rates of terbinafine use across Europe were generally low to moderate, with clear seasonal variation and a temporary decline during the COVID-19 pandemic. Older adults and males had the highest incidence, although sex differences varied by country. Most terbinafine initiators were adults, with dermatophytosis, particularly onychomycosis, being the most common indication. Treatment was predominantly monotherapy, with topical terbinafine used for superficial infections and systemic therapy for onychomycosis. A substantial proportion of individuals continued with additional antifungal treatment. No coded evidence of antifungal resistance was identified. These findings highlight the widespread use of terbinafine in Europe and underscore the value of real-world data for monitoring utilisation patterns. Ongoing surveillance is warranted to detect emerging trends, support regulatory decision-making, and inform strategies to optimise antifungal stewardship and patient care.

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DISCLOSURE

This study was funded by the European Medicines Agency (EMA) and performed via DARWIN EU® (EUPAS1000000790). EMA was involved in conceiving the research, objectives, and reviewing the study protocol and the study report including the results. Data partners do not have an investigator role. They execute analytical code at their respective data sources, review, and approve their results. This communication represents the DARWIN EU® Coordination Centre only and cannot be interpreted as reflecting those of the EMA or the European Medicines Regulatory Network.

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