Terbinol®

terbinafine

BROAD SPECTRUM ANTIFUNGAL

First line treatment for severe and complicated skin & nail fungal infections

Adults	250 mg / day
Children: Adjusted scheme according to weight.	
12 to 20 kg	62,5 mg / day
20 to 40 kg	125 mg / day
more than 40 kg	250 mg / day

The duration of treatment depends on the indication and the severity of the infection.

Onychomycosis (hands and feet):	Treatment of 6 weeks to 3 months
Tinea pedis:	Treatment of 2 to 6 weeks
Tinea corporis, Tinea cruris and Candidose:	Treatment of 2 to 4 weeks
Tinea capitis:	Treatment of 4 to 6 weeks
Pityriasis versicolore:	Treatment of 2 weeks

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Dafra PHARMA

Setting the standard

www.dafrapharma.com

Terbinol®

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EUROPEAN GMP

BROAD SPECTRUM ANTIFUNGAL

First line treatment for severe and complicated skin & nail fungal infections

250 mg tablets

- ✓ Onychomycosis (toe or finger nails)
- ✓ Tinea corporis
- ✓ Tinea cruris
- ✓ Tinea pedis
- ✓ Treatment of skin infections caused by yeast
- ✓ Pityriasis versicolor

WHEN AN ORAL TREATMENT SEEMS APPROPRIATE DUE TO THE PLACE, SEVERITY OR SCOPE OF THE INFECTION

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PRESENTATIONS

Breakable tablet with 250 mg of terbinafine. Box of 14 tablets.

Excipients: carmellose sodium, microcrystalline cellulose, hypromellose, magnesium stearate, anhydrous colloidal silica.

INDICATIONS / USAGE POSSIBILITIES

- **Nail fungal infections** (Onychomycosis / onychia and paronychia).
- **Cutaneous dermatophytosis** (ringworm of the glabrous skin, palmoplantar keratoderma, interdigital and plantar intertrigo).
- **Skin candidiasis**
  Especially when these infections cannot be treated locally due to the extent of the lesions or resistance to the usual local antifungal treatments.

An oral antifungal treatment is chosen depending on the location, severity and extent of the infection. However, terbinafine administered per os is ineffective in tinea versicolor and vaginal candidiasis.

Antifungal spectrum

Dermatophytes such as Trichophyton spp. (for example, T. rubrum, T. ton-surans, T. mentagrophytes, T. verrucosum, T. violaceum), Microsporum canis and Epidermophyton floccosum/ Filamentous fungi (Tinea corporis, Tinea cruris, Tinea pedis and Tinea capitis)/Candida yeasts (Candida albicans).

USUAL TREATMENT REGIMENS

The duration of treatment depends on the disease: the therapeutic effect is assessed 4 to 6 weeks after the end of the treatment. Care must be taken that the treatment is administered for a sufficiently long time, because a too-short treatment duration and/or irregular administration of the medication incur a risk of recurrence.

Treatment duration

Onychomycosis (hands and feet): 6 weeks to 3 months. Tinea pedis: 2 to 6 weeks.

Tinea corporis, tinea cruris and candidose: 2 to 4 weeks. Tinea capitis: 4 to 6 weeks. Pityriasis versicolore: 2 weeks.

CONTRA-INDICATIONS

Known hypersensitivity to terbinafine or one of the excipients of Terbinol® tablets.

WARNINGS AND PRECAUTIONS

Terbinol® in the oral form should only be used to treat fungal infections when they cannot be treated topically. Use in children <20 kg is not recommended.

PREGNANCY / BREASTFEEDING

Terbinol® tablets should not be used in pregnancy except in case of necessity. Although terbinafine only passes into breast milk in small quantities, mothers who take Terbinol® should abstain from breastfeeding.

UNDESIRABLE EFFECTS

In most cases, undesirable effects are temporary: taste changes and digestive problems.

Rarely: joint and muscle pain, hepatitis, hepatic injury. Exceptionally: blood count abnormality, allergic skin reaction.

OVERDOSE

A few cases of overdose up to 5 g have been reported. The patients complained of the following symptoms: headache, nausea, epigastric pain and vertigo. The recommended treatment consists of eliminating the active substance by oral administration of activated charcoal and, if necessary, adjuvant symptomatic treatment.

PHARMACOLOGICAL PROPERTIES

Code ATC: D01BA02.

Mechanism of action/Pharmacodynamics

Terbinafine is a broad spectrum antifungal of the allylamine class. It exerts a fungicidal effect on dermatophytes, mold and certain dimorphic fungi. Its effect on yeast is fungicidal or fungistatic depending on the species in question. Terbinafine acts in a specific early phase of ergosterol biosynthesis of the fungal cell membrane. Inhibition of the squalene-epoxidase enzyme leads to a deficiency in ergosterol and an intracellular accumula-tion of squalene, which leads to lysis of the fungal cell, primarily due to the disruption of the membrane function. Terbinafine acts by inhibiting squalene- epoxidase in the fungal cell membrane. Squalene-epoxidase is not part of the cytochrome. P450 system. Terbinafine therefore has no influence on metabolism of hormones or other drugs.

Pharmacokinetics

- A single oral dose of 250 mg of terbinafine leads to a mean plasma concentration peak within two hours after administration. The absorption half-life is 0.8 hours and the distribution half-life is 4.6 hours.
- Terbinafine is strongly bound to plasma proteins (99%) and diffuses rapidly through the dermis and concentrates in the lipophilic stratum corneum. Terbinafine is also excreted in the sebum, and so reaches high concentrations in the hair follicles, scalp and in skin rich in sebum.
- There is also proof that terbinafine is distributed in the nails in the first weeks of treatment.
- Biotransformation into metabolites gives rise to metabolites that lack antifungal activity, which are mainly eliminated in the urine. The elimination half-life is 17 hours.
- The rate of elimination may be slowed in patients with kidney or liver impairment, which can lead to higher plasma concentrations.
- The bioavailability of terbinafine is moderately influenced by food intake and does not require adjusting the dosage.
- In patients with moderate to severe liver impairment, single-dose pharmacokinetic studies have shown that terbinafine clearance may be reduced by 50%.

STORAGE

Store below 25-30 °C, in the original package, protected from light. Keep out of reach and sight of children. Do not use after the expiry date indicated after «EXP» on the container.