Terbinol®

terbinafine

BROAD SPECTRUM ANTIFUNGAL

CREAM:

Topical treatment of dermatological infections and superficial mycoses

Ringworm – Athlete's foot – Eczema – Pityriasis
Fungal infections of the skin folds – Onychomycosis
Superficial mycoses – Cutaneous candidiasis – Malassezia

The product is applied once or twice per day depending on the indication.
The affected areas should be cleaned and carefully dried before applying TERBINOL®.

TABLETS:

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

Onychomycosis (hands and feet) – Tinea pedis – Tinea cruris – Tinea corporis
Treatment of skin infections – caused by yeast – Pityriasis versicolore

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 length of the treatment varies depending on the indication and the severity of the infection.

The clinical symptoms improve within days. Irregular application or early discontinuation of the treatment increases the risk of relapse.

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3FITERALLE 2021

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Terbinol®

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BROAD SPECTRUM ANTIFUNGAL TREATMENTS

First line treatment of fungal infections caused by dermatophytes or yeasts

CREAM : Localized cutaneous mycoses, eczema, ringworm, athlete's foot, fungal infections of the skin folds and onychomycosis

TABLETS: More severe and/or complicated fungal infections of the skin and nails

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PRESENTATION

- **TERBINOL® Cream:** 15g tube with 1% terbinafine hydrochloride.
- **TERBINOL® Tablets:** Breakable tablet with 250 mg of terbinafine. Box of 14 tablets.

INDICATIONS/POSSIBILITIES FOR USE

1. Dermatophytosis
- Dermatophytosis of hairless skin,
- Genitocrural intertrigo,
- Intertrigo of the toes (athlete's foot).

2. Cutaneous candidiasis
Cutaneous candidiasis seen in human clinical cases are usually due to Candida albicans. In certain cases, it is recommended to simultaneously treat the digestive tract.

3. Tinea versicolor

4. Adjunctive treatment of the onyxis and perionyxis (onychomycosis)

5. Nail fungal infections
(Onychomycosis / onychia and paronychia).

6. Cutaneous dermatophytosis
(Ringworm of the glabrous skin, palmoplantar keratoderma, interdigital and plantar intertrigo).

7. Skin candidiasis (Tablets)
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 is ineffective in tinea versicolor and vaginal candidiasis.

DOSAGE / INSTRUCTIONS FOR USE

Usual dose: adults and children aged 12 and over: **TERBINOL® cream:** may be applied once or twice daily, according to the indication. Before use, carefully clean and then dry the affected areas of skin.
Apply a thin layer of the cream to the affected areas of skin and the adjoining areas and gently rub in.
In the case of an intertriginous infection (submammary, interdigital, intergluteal, inguinal), gauze may be used to cover affected areas after applying the cream, especially during nighttime application.
TERBINOL® tablets: Adults: 250 mg 1x/day. Adolescents > 40 kg (>12 ans): 250mg 1x/day. children between 20 and 40 kg (5 – 12 year): 125 mg 1x/day. Children <20 kg (< 5 ans): 62,5mg 1x/day. The drug should only be used when no therapeutic alternatives are available and when the benefit takes precedence over the presumed risk.

USUAL TREATMENT REGIMENS

TERBINOL® cream: The duration of treatment is based on the pathology: The therapeutic effect is evaluated 4 to 6 weeks after the end of treatment. Intertrigo between the toes caused by dermatophytes: 1 application per day for 1 week. Dermatophytosis and cutaneous candidiasis: 1 application per day for 1 week. Tinea versicolor: 1 to 2 applications per day for 2 weeks. The clinical symptoms usually disappear in several days. Irregular application or early discontinuation of the treatment increases the risk of a relapse. If no sign of cure is seen after one week, the diagnosis must be reconsidered.
TERBINOL® tablets: 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.

CONTRAINDICATIONS

Hypersensitivity to terbinafine or one of the excipients in the cream, spray and tablets.

WARNINGS AND PRECAUTIONS

TERBINOL® cream is intended for external use only. Avoid all contact with the eyes.

TERBINOL® tablets should only be used to treat fungal infections when they cannot be treated topically. Use in children <20 kg is not recommended. Take special care with TERBINOL® Tablets if you suffer from liver or kidney disease; from psoriasis (scaling skin disease) or lupus erythematosus (auto-immune disorder, affecting the skin, joints, kidneys & brain), as it may worsen whilst you are taking TERBINOL® Tablets.

PREGNANCY AND LACTATION

Since the availability of the topical terbinafine into the systemic circulation is minimal after dermal application, it is thought that fetus is not affected with this fraction. This product should not be applied on breast skin of nursing mothers. **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.

SIDE EFFECTS

TERBINOL® cream: Applications sometimes causes local reactions such as redness, pruritus and a burning feeling but these reactions only rarely require treatment to be discontinued. However, a distinction should be made between these benign symptoms and allergic reactions which occur rarely but which require treatment to be discontinued. This type of allergic reaction can be accompanied by redness, papules, vesicles and pruritus which may also manifest beyond the area of contact (these are known as diffusion reactions).

TERBINOL® tablets: 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

TERBINOL® tablets: A few cases of overdose up to 5g 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

PHARMACODYNAMICS

Terbinafine is a broad-spectrum antimycotic agent of the class of allylamine active principles. It has a fungicidal action on dermatophytes, molds and certain dimorphic fungi. Its action on yeasts is fungicidal or fungistatic according to the particular species.

PHARMACOKINETICS

TERBINOL® cream:

After local application, terbinafine penetrates into the skin and accumulates in the stratum corneum. Following 7 days of topical application, terbinafine can be measured at fungicidal concentrations in the stratum corneum for an additional 7 days. In humans, less than 5% of the dose applied topically is absorbed. Systemic exposure during local therapy is thus very low.

TERBINOL® tablets:

- 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%.
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STORAGE

TERBINOL® cream: Store below 30°C, in the original package. Keep out of reach and sight of children. Do not use after the expiry date, stated on the packaging. The expiry date refers to the last day of that month.

TERBINOL® tablets: 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.