

# TERBIAIM Tablets/Cream

Terbinafine (USP Specification)

طرہی ایم گولیاں کریم  
تربینا فائین

## COMPOSITION

Tablets: Terbinafine (as hydrochloride) 125 mg/tablet

Tablets: Terbinafine (as hydrochloride) 250 mg/tablet

Terbinaim Cream: Each gram contains: Terbinafine (as hydrochloride) ..... 10mg

## PROPERTIES:

Terbinafine is an allylamine which has a broad spectrum of antifungal activity. At low concentrations terbinafine is fungicidal against dermatophytes, molds and certain dimorphic fungi. The activity against yeasts is fungicidal or fungistatic, depending on the species. Terbinafine interferes specifically with fungal sterol biosynthesis at an early step. This leads to a deficiency in ergosterol and to an intracellular accumulation of squalene, resulting in fungal cell death inhibition of squalene. Death of the cell is due to squalene epoxidase in the fungal cell membrane. The enzyme squalene epoxidase is not linked to the cytochrome P450 system. Terbinafine does not influence the metabolism of hormones or other drugs. When given orally the drug concentrates in skin, hair and nails at levels associated with fungicidal activity. When given topically the drug has a rapid onset of action and can be effective with a short treatment duration.

## PHARMACOKINETICS:

A single oral dose of 250mg terbinafine (2 tablets) results in peak plasma concentrations of 0.97ug/ml within two hours of administration. The absorption half-life is 0.8 hours and the distribution half-life is 4.6 hours. The bioavailability of terbinafine is moderately affected by food, but not sufficiently to require dosing adjustments. Terbinafine binds strongly to plasma proteins (99%). It rapidly diffuses through the dermis and concentrates in the lipophilic stratum corneum. Terbinafine is also secreted in sebum, thus achieving high concentrations in hair follicles, hair and sebum-rich skin. There is also evidence that into the nail plate in the first few weeks after commencing therapy. Biotransformation results in metabolites with no antifungal activity which are excreted predominantly in the urine. The terminal elimination half-life is 1-7 concentration of Terbinaim have been observed, but the elimination rate may be reduced in patients with renal or hepatic impairment, resulting in higher blood levels of Terbinafine.

## INDICATIONS:

Fungal infections of the skins, hair and nails caused by dermatophytes such as Trichophyton (e.g T Rubrum, T. Mentagrophytes, T. Verrucosum, T. Tonsurans, T. Violceumy, Microsporium canis and Epide miophyton foccosum. Oral Terbinaim is indicated in the treatment of ringworm (tinea corporis, tinea cruris tinea pedis and tinea capitis) and yeast infection of the skin caused by the genus Candida (e.g. Candida albicans) where oral therapy is considered appropriate owing to the site, severity or extent of the infection. Onychomycosis (fungal infection of the nail) caused by dermatophyte fungi.

Note: in contrast to topical Terbinaim, oral Terbinaim is not effective in Pityriasis versicolor.

## DOSAGE AND ADMINISTRATION:

The duration of treatment varies according to the indication and the severity of the infection.

### Tablets:

#### Children:

No data are available in children under two years of age (usually <12 kg).

Children weighing <20kg

Children weighing 20 to 40 kg

Children weighing >40kg

62.5mg (half tablet) once daily

125 mg (one tablet) once daily

250 mg (two tablets) once daily

#### Adults:

250mg (two 125mg tablets) once a day

### Skin Infections:

Likely duration of treatment:

Tinea pedis (interdigital, planter/moccasin type): 2 to 6 weeks

Tinea corporis, cruris: 2 to 4 weeks

Cutaneous candidiasis: 2 to 4 weeks

### Hair and scalp Infections:

Likely duration of treatment

Tinea capitis: 4 weeks

Tinea capitis occurs primarily in children.

### Onychomycosis:

For most patients the duration for successful treatment is between 6 weeks to 3 months. Less than 3 months can be anticipated for the treatment of finger nail infections or infections of toe nails other than of the big toes particularly in patients of younger age with a normal rate of hall outgrowth. In the remaining cases 3 months of therapy is usually sufficient, though some patients, particularly those with nail infection of the big toes, may require treatment of 6 months or longer. Poor nail outgrowth, as observed during the first weeks of therapy may enable identification of those patients in whom treatment longer than 3 months indicated, in fungal nail infections the optimal clinical effect is seen some months after mycological cure and cessation of treatment. This is related to the period required for outgrowth of healthy nail tissue.

### Likely duration of treatment:

Tinea corporis, cruris

1 weeks

Tinea pedis:

1 weeks

Cutaneous candidiasis

1 weeks

Pityriasis versicolor

2 weeks

Relief of clinical symptoms usually occurs within a few days, irregular use or premature discontinuation of treatment carries the risk of recurrence. If there are no signs of improvement after two weeks the diagnosis should be verified.

### Use of Terbinaim in the elderly:

There is no evidence to suggest that elderly patients require different dosages or experience side effects different from those in younger patients. When using tablets in this age group, the possibility of pre-existing impairment of liver or kidney function should be considered (see Precautions)

### Use of Terbinaim in children:

In children above 2 years of age, Oral Terbinaim has been found to be well tolerated.

### Precautions:

Tablets: Patients with pre-existing stable chronic liver dysfunction or impaired renal function (creatinine clearance less than 50 ml/minor serum creatinine of more than 300 umol/L) should receive half the normal dose (see also: Side effects').

### Tablets Pregnancy and lactation:

Fetal toxicity and fertility studies in animals suggest no severe effects. Since clinical experience in pregnant women is very limited. Oral Terbiain should not be used during pregnancy unless the potential benefits outweigh any potential risks. Terbinafine is excreted in breast milk; therefore mothers receiving oral treatment with Terbiain should not breast-feed. If treatment is topical, the small amounts absorbed through the skin are unlikely to affect the infant.

### INTERACTIONS:

According to the results from studies undertaken in vitro and healthy volunteers, terbinafine shows negligible potential for inhibiting or inducing the clearance of drugs that are metabolized via the cytochrome P450 system (eg. Cyclosporin, tobutamide, or oral contraceptives). Some cases of menstrual irregularities have been reported in patients taking Terbiain concomitantly with oral contraceptives, although the incidence of these disorders remains within the background incidence of patients taking oral contraceptives alone. On the other hand, the plasma clearance of terbinafine may be accelerated by drugs which induce metabolism (such as rifampicin) and may be inhibited by drugs which inhibit cytochrome P450 (such as cimetidine). Where co-administration of such agents is necessary, the dosage of Terbiain may need to be adjusted accordingly.

### SIDE EFFECTS:

In general Terbiain is well tolerated. Side effects are mild to moderate and transient. The most common are gastrointestinal symptoms (feeling of fullness, loss appetite, dyspepsia, nausea, mild abdominal pain, diarrhoea) or non-serious forms of skin reactions (rash, urticaria). Isolated cases of serious skin reactions (e.g. Stevens-Johnson syndrome, toxic epidermal necrolysis) have been reported. If progressive skin rash occurs, Terbiain treatment should be discontinued. Rarely, Terbiain may cause taste disturbances, including taste loss, which recover within several weeks after discontinuation of the drug. Isolated cases of significant hepatobiliary dysfunction have been reported. Although a causal relationship to the drug has not been established, treatment with Terbiain should be discontinued if hepatobiliary dysfunction develops. Isolated cases of hematological disorders such as neutropenia or thrombocytopenia have been reported.

### OVER DOSAGE:

A single-case of accidental overdosage has reported. After intake of 4 g, the patient presented with nausea, epigastric pain and dizziness. The patient made a full recovery. The recommended treatment of overdosage consists of eliminating the drug primarily by the administration of activated charcoal and if needed, of symptomatic supportive therapy.

### CREAM:

Terbinafine is used to treat a variety of fungal skin infections such as ringworm, athlete's foot, and jock itch. This medication is also used to treat a skin condition known as pityriasis (tinea versicolor), a fungal infection that causes a lightening or darkening of the skin of the neck, chest, arms, or legs. Terbinafine is an antifungal that works by preventing the growth of fungus.

### How to use cream

Use this medication on the skin only. Clean and thoroughly dry the area to be treated. Apply enough medication to wet the skin on and around the affected area, usually once or twice daily as directed by the doctor. Wash your hands after using unless the area being treated includes the hands. Do not wrap, cover, or bandage the area unless directed to do so by your doctor.

Do not use the medication in the eyes, nose, or mouth, or inside the vagina. If you do get the medication in those areas, flush with plenty of water.

### Side effects:

Burning, irritation, redness, or itching at the application site may occur. If any of these effects persist or worsen or if any of these unlikely but serious side effects occur, blistering/swelling/oozing at the application site notify the doctor. A very serious allergic reaction to this drug is rare. However, seek immediate medical attention if you notice any of the following symptoms of a serious allergic reaction: rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing. **Terbiain-Facts**

### The doctor cares for the patients' health..... his advice should be carefully followed.

Terbiain has been clinically proven to have high cure rates (over 90%) in most type of dermatophyte infections of the skin on the foot, body hair and fungal infection of the nails can now be treated with Terbiain. Studies have shown that in fungal nail infections the best clinical effect with Terbiain is seen in 3 to 6 months after treatment. This is related to the period required for outgrowth of healthy nail tissue.

### For fungal nail infections (Onychomycosis)

In most patients with fungal nail and to nail infections duration of Terbiain treatment is usually 6 weeks to 3 months

Finger nail infection 6 weeks  
Toe nail infection 12 weeks

However, in some cases of big toenail infection the duration of Terbiain treatment may expand upto 6 months. Treatment of fungal nail infection with Terbiain brings about cure with the result that a new healthy nail grows from the nail bed after few months of stopping the treatment.

### Packing: 10g tube/ pack

Terbinafine 125 mg=10x1s Tab/pack  
Terbinafine 250 mg=10x1s Tab/pack  
Terbinafine cream=10 gm/ pack 1x1s tube /pack

### PRECAUTION:

- Use as prescribed by the physician.
- Keep out of the reach of children.
- Store at room temperature.
- Protect from direct sunlight, heat & moisture

ہدایات:

دواؤ الکڑکی ہدایت کے مطابق استعمال کریں۔

بچوں کی پہنچ سے دور رکھیں۔

کمرے کے درجہ حرارت پر رکھیں۔

سورج کی روشنی، گرمی اور نمی سے محفوظ رکھیں۔



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