

# Terbitac

## Terbinafine

### Composition

**Terbitac Tablet:** Each Tablet contains Terbinafine Hydrochloride BP equivalent to Terbinafine 250 mg.

**Terbitac 1% Cream:** Each gram cream contains Terbinafine Hydrochloride BP 10 mg.

### Pharmacology

Terbinafine, an allylamine antifungal, inhibits biosynthesis of ergosterol (an essential component of fungal cell membrane) via inhibition of squalene epoxidase enzyme. This results in fungal cell death primarily due to the increased membrane permeability mediated by the accumulation of high concentrations of squalene but not due to ergosterol deficiency. Depending on the concentration of the drug and the fungal species test in vitro, Terbinafine Hydrochloride may be fungicidal. However, the clinical significance of in vitro data is unknown. Terbinafine has been shown to be active against most strains of the following microorganisms both in vitro and in clinical infections: *Trichophyton mentagrophyte*, *Trichophyton rubrum*.

### Indication

Fungal infections of the skin caused by dermatophytes such as *Trichophyton rubrum*, *Trichophyton mentagrophytes*, *Microsporum canis* and *Epidermophyton floccosum*.

### Terbinafine Tablet

- \* Onychomycosis of the toenail or fingernail due to dermatophytes
- \* Ringworm (Tinea corporis, Tinea cruris and Tinea pedis) where oral therapy is considered appropriate due to the site, severity or extent of the infection

### Terbinafine Cream

- \* Yeast infections of the skin principally caused by the genus *Candida* (e.g. *Candida albicans*)
- \* Pityriasis (tinea) versicolor due to *Pityrosporum orbiculare* (also known as *Malassezia furfur*)

### Dosage and Administration

#### Tablet:

In each indication, dose of Terbinafine Tablet is 250 mg once daily (duration of treatment varies according to the indication and the severity of infections).

Indication	Duration
Onychomycosis (Fingernail)	6 weeks
Onychomycosis (Toenail)	12 weeks
Tinea pedis	2 - 6 weeks
Tinea corporis	4 weeks
Tinea cruris	2 - 4 weeks

In case of onychomycosis, 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.

#### Cream:

Cream can be applied once or twice daily (duration of treatment varies according to the indication and the severity of infections). Cleanse and dry the affected areas thoroughly before application of Cream. Apply the Cream to the affected skin and surrounding area in thin layer and rub in lightly.

Indication	Duration
Tinea pedis	1 week
Tinea corporis, Tinea cruris	1-2 weeks
Cutaneous candidiasis	2 weeks
Pityriasis versicolor	2 weeks

Relief of clinical symptoms usually occurs within a few days. The treatment must be used regularly and for an adequate length of time. Irregular use or premature discontinuation of treatment carries the risk of recurrence. If there is no sign of improvement after two weeks, the diagnosis should be verified.

### Contraindication

Hypersensitivity to terbinafine or any of the excipients contained in the tablet or cream.

### Precaution

Terbinafine cream is for external use only. Contact with the eyes should be avoided.

### Side effect

Most common side effects of tablet are headache, diarrhea, rash, dyspepsia, liver enzyme abnormalities, pruritus, taste disturbance, nausea, abdominal pain and flatulence. Occasionally may cause severe liver toxicity, change in taste or loss of taste, serious skin or allergic reactions etc. Side effects of Cream include occasional redness, itching or stinging at the site of application; symptoms must be distinguished from allergic which are rare but require discontinuation of treatment.

### Drug interaction

When taken orally Terbinafine is an inhibitor of Cytochrome P450 2D6 isozyme and has an effect on metabolism of Desipramine, Cimetidine, Fluconazole, Cyclosporine, Rifampin and Caffeine. There is no known drug interaction when Terbinafine is taken topically.

### Use in Pregnancy and Lactation

Terbinafine is a 'Pregnancy Category B' drug. There are no adequate and well-controlled studies in pregnant women. It is recommended that Terbinafine should not be initiated during pregnancy (unless the benefit outweighs the risk to the fetus). Terbinafine is present in breast milk of nursing mothers. Treatment with Terbinafine is not recommended in women who are nursing.

### Use in Children

The safety and efficacy of Terbinafine Tablet have not been established in pediatric patients with onychomycosis. The safety and efficacy of Terbinafine Cream have not been established in pediatric patients.

### Use in Elderly

Dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function and of concomitant disease or other drug therapy.

### Storage condition

**Terbitac Tablet:** Do not store above 30° C. Protect from light.

**Terbitac 1% Cream:** Do not store above 25° C. Protect from light.

Keep both the products from the reach of children.

### How supplied

**Terbitac Tablet:** Each box contains 10 Tablets in blister pack.

**Terbitac 1% Cream:** Each carton contains a tube of 10 g cream.

Manufactured by:



**Ziska Pharmaceuticals Ltd.**

Kaliakoir, Gazipur, Bangladesh