



Composition

Terbifin® Tablet: Each tablet contains Terbinafine Hydrochloride BP equivalent to Terbinafine 250 mg.

Terbifin® Cream: Each gram cream contains Terbinafine Hydrochloride BP 10 mg.

Pharmacology

Terbinafine Hydrochloride is a synthetic allylamine antifungal, which is fungicidal against dermatophytes, mold fungi and some yeasts. Terbinafine interferes with fungal ergosterol biosynthesis by inhibiting squalene epoxidase in the cell membrane. This leads to a deficiency of ergosterol and an intracellular accumulation of squalene, thus disrupting fungal membrane function and cell wall synthesis resulting in fungal cell death. Terbinafine does not inhibit cytochrome P450 activity and is weakly bound to hepatic cytochrome P450 enzymes. Terbinafine is distributed into the stratum corneum of the skin, the nail plate and hair in higher concentration than found in plasma.

Indications

Terbifin® Tablet: Dermatophyte infections of the nails, ringworm infections (including Tinea Pedis, Cruris and Corporis) where oral therapy is appropriate (due to site, severity and extent).

Terbifin® Cream: Dermatophyte infections of the skin and hair, Pityriasis (Tinea) Versicolor and yeast infections of the skin.

Other uses:

- Non-dermatophyte nail infections.
- Systemic mycoses with dimorphic and rare mold fungi.

Dosage and administration:

Terbifin® Tablet:

| Indications | Daily Dosage | Duration |
|--------------------------|--------------|-----------|
| Fingernail Onychomycosis | 250 mg daily | 6 weeks |
| Toenail Onychomycosis | 250 mg daily | 12 weeks |
| Tinea Pedis | 250 mg daily | 2-6 weeks |
| Tinea Cruris | 250 mg daily | 2-4 weeks |
| Tinea Corporis | 250 mg daily | 4 weeks |

Child: Usually for 2 weeks, Tinea Capitis, over 1 year, body-weight 10-20 kg, 62.5 mg once daily; body-weight 20-40 kg, 125 mg once daily; body-weight over 40 kg, 250 mg once daily.

Terbifin® Cream

Applied once or twice daily in

| Indications | Duration |
|-------------------------------|-----------|
| Tinea Corporis, Cruris | 1-2 weeks |
| Tinea Pedis | 1 week |
| Cutaneous Candidiasis | 2 weeks |
| Pityriasis (Tinea) Versicolor | 2 weeks |

Application of Terbifin® Cream

Clean and dry the affected areas thoroughly before application of **Terbifin®**. Apply the cream to the affected skin and surrounding area in a thin layer and rub it lightly. In case of intertriginous infections (submammary, interdigital, intergluteal inguinal) the application may be covered with a gauze strip, especially at night. Wash the hands thoroughly after application.

Contraindication

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

Warnings

Good general hygiene is necessary in conjunction with the use of Terbinafine in order to prevent reinfection (e.g. from underwear, socks, shoes etc.).

Precautions

Terbifin® cream is for external use only. Contact with eyes should be avoided.

Side Effects

Terbifin® Tablet: Abdominal discomfort, anorexia, nausea, diarrhoea, headache, rash and urticaria occasionally with arthralgia or myalgia. Less frequently taste disturbance. Rarely liver toxicity, photosensitivity, serious skin reactions etc.

Terbifin® Cream: Redness, itching or stinging; rarely allergic reactions.

Use in pregnancy and lactation: Pregnancy category B. Treatment with Terbinafine is not recommended in nursing mothers.

Use in children: **Terbifin**[®] cream appears to be an effective and well-tolerated treatment for Tinea Corporis and Tinea Cruris in children.

Use in elderly: Terbinafine appears to be safe in the elderly. The dose should be reduced by half if significant hepatic or renal impairment is present.

Drug interactions

Plasma concentration of Terbinafine is increased by *Rifampicin*. Plasma concentration of Terbinafine is decreased by *Cimetidine*.

Storage

Store below 30°C and dry place, protect from light. Keep out of the reach of children.

Packing

Terbifin[®] **Tablet:** Each box contains 12 tablets in Alu-Alu blister pack.

Terbifin[®] **Cream:** Each Tube contains 10g cream.

Manufactured by:
 **ARISTOPHARMA LTD.**
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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