Mycofree
Tablet

DRUG INTERNATIONAL LTD.

Composition : Each film coated tablet contains Terbinafine 250 mg as Terbinafine Hydrochloride USP.

Pharmacology : Terbinafine is an allylamine antifungal. Following oral administration, terbinafine is well absorbed (>70%) and the bioavailability of this tablets as a result of first-pass metabolism is approximately 40%. Peak plasma concentrations of 1 µg/mL appear within 2 hours after a single 250 mg dose. Terbinafine is > 99% bound to plasma proteins. Terbinafine is distributed to the sebum and skin. Terbinafine is extensively metabolized by at least 7 CYP isoenzymes with major contributions from CYP2C9, CYP1A2, CYP3A4, CYP2C8, and CYP2C19. Approximately 70% of the administered dose is eliminated in the urine.

Indication : Mycofree tablet is indicated for the treatment of :

- Onychomycosis of fingernails and toenails due to dermatophytes.
- Fungal infections of the skin (Tinea corporis, Tinea cruris, Tinea pedis).
- Hair and scalp infections (Tinea capitis).
- Yeast infections of the skin caused by the genus Candida (e.g. Candida albicans), where oral therapy is generally considered appropriate owing to the site, severity or extent of the infection.

Dosage and administration :

For Tinea cruris: 250mg tablet once daily for 2 to 4 weeks.

For Tinea pedis: 250mg tablet once daily for 2 to 6 weeks.

For Tinea corporis: 250mg tablet once daily for 4 weeks.

For dermatophyte infections of the finger & toenails : 250mg tablet once daily for 6 to 12 weeks. Longer treatment is necessary for toenail infections.

For skin and hair infections : 250mg tablet once daily for 2 to 6 weeks.

Or, as directed by the registered physician.

Contraindication : It is contraindicated in patients with known hypersensitivity to the drug.

Precaution : It should be used with caution in patients with impaired hepatic and renal function.

Side effects : Side effects are generally mild to moderate and transient, most common side effects are: Gastrointestinal symptoms-dyspepsia, loss of appetite, nausea, mild abdominal pain, diarrhoea, headache and dizziness.

Use in pregnancy and lactation :

Pregnancy : Pregnancy category B. It should not be used during pregnancy unless the potential benefits clearly outweigh the risk.

Lactation: It should not be given to nursing mothers because the drug is excreted in breast milk.

Use in Child : There is no data available.

Drug Interactions : Plasma concentration of Terbinafine may be increased by drugs that inhibit its metabolism by cytochrome P450, such as Cimetidine and decreased by drugs such as Rifampicin that induce cytochrome P450.

Overdose : The symptoms of overdose included nausea, vomiting, abdominal pain, dizziness, rash, frequent urination, and headache.

Storage : Store below 30°C in a dry place.

Packing : Each box contains 1 x 10's tablet in blister pack.