



Xfin[®] 1% cream

Terbinafine Hydrochloride
Antifungal

COMPOSITION

Xfin[®] : Each 5 gm Xfin[®] cream contains 50 mg Terbinafine Hydrochloride.

PHARMACOLOGY

Terbinafine is an allylamine, which has a broad spectrum of antifungal activity. At low concentration terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi. The activity against yeasts is fungicidal or fungistatic depending on the species.

Terbinafine interferes specially 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. Terbinafine acts by inhibition of squalene epoxidase in the fungal cell membrane.

The enzyme squalene epoxidase is not linked to the cytochrome P-450 system. Terbinafine does not influence the metabolism of hormones or other drugs. Less than 5% of the dose is absorbed after topical application to humans, systemic exposure is therefore very slight.

INDICATION

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

Yeast infections of the skin principally caused by the genus *Candida* (e.g. *C. albicans*).

Pityriasis (tinea) versicolor due to *Pityrosporum orbiculare* (also known as *Malassezia furfur*).

DOSAGE AND ADMINISTRATION

Xfin[®] can be applied once or twice daily. Cleanse and dry the affected areas thoroughly before application of Xfin[®]. Apply the cream to the affected skin and surrounding area in thin layer and rub in lightly.

The durations of treatment are as follows:

Tinea corporis; cruris : 1 to 2 weeks

Tinea pedis : 1 week

Cutaneous candidiasis : 2 weeks

Pityriasis versicolor : 2 weeks

Relief of clinical symptoms usually occurs within a few days. The treatment

Xfin[®]

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 AND PRECAUTION

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

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

SIDE EFFECT

Redness, itching or stinging occasionally occur at the site of application; symptoms must be distinguished from allergic which are rare but require discontinuation of treatment.

DRUG INTERACTION

There is no known drug interaction with terbinafine cream.

USE IN PREGNANCY AND LACTATION

Foetal toxicity and fertility studies in animals suggest no adverse effect. There is no clinical experience with terbinafine cream in pregnant women, therefore unless the potential benefits outweigh the potential risks, terbinafine cream should not be administered during pregnancy.

Terbinafine is excreted in breast milk and therefore mothers should not receive terbinafine whilst breast feeding.

STORAGE CONDITION

Store in a cool and dry place, away from light. Keep out of reach of children.

HOW SUPPLIED

Xfin[®] 1% cream: Tube containing 5 gm cream.

