Terbisol

Terbinafine Hydrochloride BP 1% W/W

COMPOSITION

Each gram of 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*. 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

Cream can be applied once or twice daily (duration of treatment varies according to the indication and the severity of infections). Clean 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 Hydrochloride or any of the excipients contained in the cream.

WARNING AND PRECAUTION

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

SIDE EFFECT

Side effects of cream include occasional redness, itching or stinging at the site of application.

USE IN PREGNANCY & LACTATION

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

USE IN CHILDREN

The safety and efficacy of Terbinafine Hydrochloride cream have not been established in pediatric patients.

DRUG INTERACTION

There is no known drug interaction when Terbinafine Hydrochloride is taken topically.

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.

OVERDOSE

There has been no experience of overdose with topical formulations of Terbinafine Hydrochloride.

STORAGE CONDITION

Keep below 30°C temperature in a dry place, protected from light. Do not freeze. Keep out of the reach of children.

HOW SUPPLIED

Terbisol cream: Each box contains a tube of 10 gm Terbisol cream.

02278/00

NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
Chauddagram, Cumilla, Bangladesh.