HOE
Est. 1979

TEFIN gel 1% w/w

Name and Strength of Active Substance: Terbinafine Hydrochloride 1.12% w/w (equivalent to Terbinafine 1.0% w/w).

Product Description: An opaque white viscous gel with characteristic odour.
Other ingredients: Benzyl Alcohol, Butylated Hydroxytoluene, Isopropyl Myristate, Polysorbate 20, Carbomer, Alcohol, Sodium Hydroxide, Sorbitan Laurate and Purified Water.

Route of Administration: Topical.

Pharmacodynamics: Terbinafine is an allylamine which has a broad spectrum of antifungal activity in fungal infections of the skin caused by dermatophytes such as Trichophyton (e.g. T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum), Microsporum canis and Epidermophyton floccosum. At low concentrations terbinafine is fungicidal against dermatophytes and moulds. The activity against yeasts is fungicidal (e.g. Pityrosporum orbiculare or Malassezia furfur) or fungistatic, depending on the species.

Terbinafine interferes specifically 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 P450 system. Terbinafine does not influence the metabolism of hormones or other drugs.

Pharmacokinetics: Less than 5% of the dose is absorbed after topical application to humans; systemic exposure is thus very slight. At the level of the stratum corneum, fungicidal concentrations of terbinafine can be measured up to 7 days after the last administration.

Indications: For the topical treatment of fungal infections.

Contraindications: Hypersensitivity to terbinafine, or any component in the preparation.

Adverse Effects: In a small fraction of recipients, terbinafine when applied topically may cause stinging, erythema, oedema, vesication, desquamation, pruritus and urticaria.

Drug Interaction: Unknown.

Precautions/Warnings: If irritation or sensitivity occurs, treatment should be discontinued. Do not use on children under 2 years of age except under the advice and supervision of a doctor. Avoid contact with eyes and mucous membranes (for external use only). Consult doctor or pharmacist if no improvement is seen within 2 weeks of first starting treatment.

Pregnancy and Lactation: Animal studies did not reveal any teratogenic or embryofoetotoxic potential of terbinafine. No cases of malformation in humans have been reported with terbinafine to date. However since clinical experience in pregnant women is very limited, TEFIN gel 1% w/w should only be used if clearly indicated during pregnancy.
Terbinafine is excreted in breast milk, and therefore mothers should not receive TEFIN gel 1% w/w whilst breast feeding. Infants should also not be allowed to come into contact with any treated skin, including breast.

Recommended Dosage: Apply TEFIN gel 1% w/w to the affected areas once a day, for one week. Regular applications is essential for successful treatment. Treatment should be continued for two weeks after all clinical signs have disappeared. Attention to hygiene is important in the management of fungal diseases, particularly of the folds and the feet. If no improvement is seen after 4 weeks, diagnosis should be reviewed.

Symptoms and Treatment for Overdosage and Antidote(s): After topical application to the skin terbinafine penetrates the epidermis and deeper layers of the skin but less than 0.5% of the dose is absorbed systematically. No information is available concerning overdosage in human beings following topical application.

Accidental Oral Ingestion: In case of accidental oral ingestion, routine supportive measures such as gastric lavage should be performed as soon as possible.

Packing: 15g Aluminium tube.

Storage: Store below 30ºC.
Keep out of reach of children.
Jauhi daripada kanak-kanak.
Recommended shelf-life: 3 years.

MANUFACTURED BY:
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