FINOTERB

Instructions for the medicinal product

Trade name: Finoterb.
International Nonproprietary Name: Terbinafine.
Dosage form: Cream.
Composition:
Terbinafine Hydrochloride BP 1% w/w.
Pharmacotherapeutic group: Antifungals for external use.
ATC Code: D01AE15.
Pharmacologic property:
Pharmacodynamics:
Terbinafine is an allylamine which has a broad spectrum of antifungal activity. At low concentrations terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi. The activity versus yeasts is fungicidal or fungistatic depending on the species.
Terbinafine interferes selectively with fungal sterol biosynthesis at an early stage through inhibition of the enzyme squalene epoxidase. This leads to a deficiency in ergosterol and to an intracellular accumulation of squalene in the fungal cell membrane. Both the deficiency in ergosterol and the accumulation of squalene are responsible for fungal cell death.
Terbinafine is used for the treatment of fungal infections of the skin and nails, which is caused by Trichophyton (e.g.T. rubrum, T.mentagrophytes, T. verrucosum, T. violaceum), Microsporum canis and Epidermophyton floccosum.
Pharmacokinetics:
Less than 5% of the dose is absorbed after topical application to humans: systemic exposure is therefore very slight.
Indications for use:
- The treatment of tinea pedis (athlete's foot) and tinea cruris (dhobie itch/jock itch) caused by Trichophyton (e.g. T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum) and Epidermophyton floccosum;
- Yeast infections of the skin, mainly those caused genus Candida (e.g., Candida albicans), in particular diaper rash;
- Colorful lichen (Pityriasis versicolor), called Pityrosporum orbiculare (also known as Malassezia furfur).
- **Contra-indications:**
- Hypersensitivity to terbinafine or to any of the excipients contained in the cream.

Precautions: Finoterb cream should not be used during pregnancy, unless clearly necessary. Terbinafine is excreted in breast milk. Therefore mothers should not use Finoterb whilst breast-feeding.
Infants must not be allowed to come into contact with any treated skin, including the breast.The experience with topical Finoterb in children is still limited and its use in children under 12 years cannot therefore be recommended.
Dosage and directions for use:
Finoterb cream can be applied once or twice daily.
For external use.
Cleanse and dry the affected areas thoroughly before application of Finoterb. Apply the cream to the affected skin and surrounding area in a thin layer and rub in lightly. In the case of intertriginous infections (submammary, interdigital, intergluteal, inguinal) the application may be covered with a gauze strip, especially at night.
Duration of treatment is 1 week for tinea pedis and tinea cruris. Relief of clinical symptoms usually occurs within a few days. Irregular use or premature discontinuation of treatment carries the risk of recurrence. If there are no signs of improvement after two weeks, the diagnosis should be verified by a physician.
Side-effects:
Local symptoms such as pruritis, skin exfoliation, application site pain, application site irritation, pigmentation disorder, skin burning sensation, erythema and scab may occur at the site of application.
Overdose:
The low systemic absorption of topical Finoterb cream renders overdosage extremely unlikely.
Symptoms of accidental ingestion of the contents of one tube: include headache, nausea, epigastric pain and dizziness.
Treatment: activated charcoal, if necessary, symptomatic supportive therapy.
Drug interaction:
There are no known drug interactions with Finoterb.
Cautions:
Finoterb cream is for external use only. Contact with the eyes should be avoided. May be irritating to the eyes. In case of accidental contact with the eyes, rinse the eyes thoroughly with running water.
Presentation:
20 gram tube with instruction for use in carton box.
Storage:
Keep in dry place, protected from light at a temperature below 25°C. Keep out of reach of children.
Shelf life:
Labeled. Do not use after expiry date.
Distribution Condition:
Non-prescribed medicine.

VEGAPHARM

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