

COMPOSITION:

Cream:

Each 1 gm contains Terbinafine Hydrochloride (Ph Eur) 10 mg.

CLINICAL PHARMACOLOGY:

Terbinafine is an allylamine derivative which has a broad spectrum of antifungal activity. At low concentration terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi. Its activity against yeasts is fungicidal or fungistatic, depending on the species. Terbinafine interferes specifically with fungal ergosterol 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. When given topically, the drug has a rapid onset of action and can be effective with short treatment duration.

INDICATIONS:

- RIATEBIFINE cream is indicated in the treatment of fungal infections of the skin caused by Trichophyton (e.g. T. rubrum, T. mentagrophytes, T. verrucosum and T. violaceum), Microsporum canis and Epidermophyton floccosum.
- RIATEBIFINE cream is also indicated in the treatment of infections caused by yeasts (candidoses of the skin) and Pityriasis (tinea) versicolor due to pityrosporum orbiculare.

CONTRAINDICATIONS:

Hypersensitivity to terbinafine or any other component of the formulation.

PRECAUTIONS:

Contact with eye should be avoided.

ADVERSE REACTIONS:

Redness, itching or stinging occasionally occur at the site of application but it is rare that these complaints cause the treatment to be stopped. These harmless reactions must be distinguished from allergic reactions which are rare but require discontinuation.

USE DURING PREGNANCY AND LACTATION:

RIATEBIFINE cream can be used only under

medical authorization during pregnancy and lactation.

METHOD OF USE:

Cleanse and dry the affected areas thoroughly before treating with RIATEBIFINE. Apply 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 and inguinal) the application may be covered with gauze especially at night.

DOSAGE:

For adults and children above 12 years:

- Tinea corporis, Tinea cruris & Tinea pedis: once a day for one week.
- Cutaneous candidiasis: 1-2 times a day for one week.
- Pityriasis versicolor: 1-2 times a day for two weeks.

STORAGE:

Store at room temperature (15-25) °C.

Do not use the drug after the expiry date printed on the package.

PRESENTATION:

Cream: 15 g Aluminium tube.

For External Use Only

This is a medicament

- A medicament is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments
out of the reach of children
Council of Arab Health Ministers
Union of Arab Pharmacists



Manufactured by RIYADH PHARMA
Medical and Cosmetic Products Co. Ltd.
Riyadh, Saudi Arabia.

