

DESCRIPTION

Mycofin[®] cream is the preparation of Terbinafine Hydrochloride, which is a synthetic antifungal compound. Terbinafine is an allylamine that has a broad-spectrum antifungal activity. At low concentrations Terbinafine is fungicidal against dermatophytes, moulds and certain dimorphic fungi. The activity against yeasts is fungicidal or fungistatic depending on the species. Terbinafine interferes with fungal sterol biosynthesis and it acts by inhibition of squalene epoxidase in the fungal cell membrane.

INDICATIONS

- Fungal infections of skin caused by dermatophytes such as Trichophyton (e.g. T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum) and Epidermophyton floccosum.
- Yeast infections of the skin, principally those caused by Candida albicans.
- Pityriasis (tinea) versicolor due to pityrosporum orbiculare (also known as malassezia furfur).

DOSAGE AND DIRECTION FOR USE

Mycofin[®] cream can be applied once or twice daily. Cleanse and dry the affected areas thoroughly before treating with Mycofin[®] cream. 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 gauze, especially at night.

DURATION OF TREATMENT

- Tinea corporis / cruris (ringworm of the body, jock itch): 1 to 2 weeks
- Tinea pedis (athlete's foot): 1 week

(One week of treatment is normally sufficient if the cream is applied twice daily).

- Cutaneous candidiasis (skin thrush): 1 to 2 weeks
- Pityriasis versicolor: 2 weeks

USE IN CHILDREN

Not recommended.

CONTRAINDICATION

Mycofin[®] cream is contraindicated in individuals who have known or suspected hypersensitivity to terbinafine or any of its components.

USE IN PREGNANCY & LACTATION

PREGNANCY: No adequate data available regarding uses of terbinafine in pregnancy. It can be used in pregnancy only if potential benefit outweighs risks.

LACTATION: It is excreted in human milk. It is advised to avoid in lactating women.

PRECAUTIONS

Mycofin® cream is only for external use. Contact with eyes should be avoided.

SIDE EFFECTS

Redness, itching or stinging may occur at the site of application. These symptoms must be distinguished from allergic reaction that are rare but require discontinuation.

DRUG INTERACTION

Potential interactions between terbinafine and other drugs have not been systematically evaluated.

PHARMACEUTICAL PRECAUTIONS

Do not store above 30 °C temperature. Keep away from light and wet place. Keep out of reach of children.

PACKAGING

Mycofin® 5 g Cream: Tube containing 5 g cream. Each gram cream contains Terbinafine Hydrochloride BP 10 mg.

Mycofin® 10 g Cream: Tube containing 10 g cream. Each gram cream contains Terbinafine Hydrochloride BP 10 mg.

SK+F

Manufactured by

ESKAYEF PHARMACEUTICALS LTD.

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