MYCODERM 1% Cream

(Terbinafine Hydrochloride Cream JP)

مائیکوڈرم 1% کریم

(ٹربینافین ہائیڈروکلورائیڈ کریم جے پی)

COMPOSITION:
Each gram cream contains:
Terbinafine HCl JP … 10mg. (1% w/w)
[JP Specs.]

CLINICAL PHARMACOLOGY:
MECHANISM OF ACTION: Terbinafine is an allylamine which has a broad spectrum of activity against fungal pathogens of the skin, hair and nails including dermatophytes. At low concentrations 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 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, 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.

PHARMACOKINETIC PROPERTIES: Less than 5% of the dose is absorbed after topical application to humans; systemic exposure is therefore very slight.

INDICATIONS: Mycoderm cream is indicated for yeast infections of the skin, principally those caused by the genus Candida (e.g. C. albicans) and Pityriasis (tinea) versicolor due to Pityrosporum orbiculare (also known as Malassezia furfur).

CONTRA-INDICATIONS:
If you are allergic (hypersensitive) to any of the ingredients in the product.
The cream is not recommended for use on children.

DOSAGE AND ADMINISTRATION: Mycoderm Cream can be applied once or twice daily.
Duration and frequency of treatment: The likely duration of each treatment is as follows:
Tinea corporis, cruris: 1 to 2 weeks
Tinea pedis: 1 week
Cutaneous candidiasis: 2 weeks
Pityriasis versicolor: 2 weeks
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.
Dosing in special populations:
Paediatric population: The experience with topical Mycoderm in children is still limited and its use cannot therefore be recommended.
Elderly patients: There is no evidence to suggest that elderly patients require different dosages or experience side- effects different to those of younger patients.

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Method of administration: For cutaneous use. Cleanse and dry the affected areas thoroughly before application of Mycoderm. 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.

OVERDOSAGE: The low systemic absorption of topical Terbinafine Cream renders overdosage extremely unlikely. Accidental ingestion of the contents of one 30g tube of Mycoderm Cream, which contains 300mg Terbinafine Hydrochloride, is comparable to one Mycoderm 250mg tablet (adult oral unit dose). Should a larger amount of Mycoderm Cream be inadvertently ingested, adverse effects similar to those observed with an overdosage of Mycoderm tablets are to be expected.These include headache, nausea, epigastric pain and dizziness. If accidentally ingested, the recommended treatment of overdosage consists of eliminating the drug, primarily by the administration of activated charcoal, and giving symptomatic supportive therapy, if needed.

WARNINGS & PRECAUTIONS: Mycoderm 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. Mycoderm Cream contains cetyl alcohol and cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

SPECIAL POPULATION:
Pregnancy: Foetal toxicity and fertility studies in animals suggest no adverse effects. There is no clinical experience with Mycoderm Cream in pregnant women. Mycoderm Cream should not be used during pregnancy, unless clearly necessary.
Lactation: Terbinafine is excreted in breast milk. Therefore mothers should not use Mycoderm Cream while breast-feeding. Infants must not be allowed to come into contact with any treated skin, including the breast.
Fertility: No effects of Terbinafine on fertility have been seen in animal studies.

SIDE EFFECTS: The following side effects have been reported with Mycoderm Cream however, treatment rarely has to be discontinued for this reason.
Common (likely to affect 1 to 10 in every 100 patients): Flaking or peeling of the skin (skin exfoliation) and itching (pruritus).
Uncommon (likely to affect 1 to 10 in every 1,000 patients): Skin lesion, scab, skin disorder, change in the color of the skin (pigmentation disorder), redness of the skin (erythema), skin burning sensation, pain, application site pain and application site irritation.
Rare: (may affect up to 1 in 1000 people): Eye irritation, dry skin, contact dermatitis, eczema and worsening of symptoms.

INTERACTION WITH OTHER DRUGS: No drug interactions are known to date.

INSTRUCTIONS: FOR EXTERNAL USE ONLY. Store below 30° C. Protect from heat and light. Keep out of the reach of children.

PRESENTATION: Mycoderm (Terbinafine) Cream 1% is available in pack size of 10g.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: صرف بیرونی استعمال کیلئے۔ ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی اور روشنی سے بچائیں۔ بچوں کی پہنچ سے دور رکھیں۔

Manufactured by:
NABIQASIM INDUSTRIES (PVT.) LTD.
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