

BETA-MICOTER® Cream

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about BETA-MICOTER

BETA-MICOTER cream for topical use contains clotrimazole 1% and betamethasone 0.05% (as betamethasone dipropionate) with the following excipients: vaseline, glycol palmito stearate, methyl paraben, propyl paraben, and purified water.

Clotrimazole is a broad spectrum imidazole antifungal active against dermatophytes and yeasts. It acts over the cellular membrane of fungi, thereby causing a loss of cellular content.

Betamethasone is a topical corticosteroid sharing anti-inflammatory and anti-pruritic actions. It relieves inflammatory symptoms such as pruritus, erythema and edema and other discomforts of fungal infections.

BETA-MICOTER is indicated for the topical treatment of dermatomycoses complicated by inflammatory and/or pruritic manifestations such as tinea pedis (athlete's foot), tinea cruris (jock itch, fungal infection of the groin), tinea corporis (fungal infection of the body) due to *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, *Trichophyton rubrum*, *Microsporum canis*, and candidiasis due to *Candida albicans*.

The way to use BETA MICOTER

Use as directed. BETA MICOTER should be applied sparingly and rubbed gently into the cleansed, affected area and surrounding skin twice a day (in the morning and in the evening).

Duration of treatment

Clinical improvement and relief of pruritus and erythema usually occur within 3–5 days; however, mycologic cures generally require prolonged therapy, especially in the treatment of tinea pedis, and therapy should be continued for 2 weeks in the treatment of tinea cruris, tinea corporis, or candidiasis, and for 4 weeks in the treatment of tinea pedis. Notify your doctor if clinical improvement does not occur after 1 week in the treatment of tinea cruris, tinea corporis and candidiasis, or after 2 weeks in the treatment of tinea pedis.

In case of overdose

Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects.

If you suspect an overdose, irritation develops, or if the cream has been ingested, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Apply the missed dose as soon as you remember unless the next application is near. Go on applying the next scheduled dose as directed. Do not apply a double dose at once.

Contraindications

This drug is contraindicated in the following conditions:

- Hypersensitivity to any of the components, to other corticosteroids or to imidazoles.
- Bacterial or viral infection involving the skin such as syphilitic or tubercular infection, vaccinia, chicken pox, herpes zoster, herpes simplex, molluscum contagiosum, acne vulgaris, acne rosacea, and in case of diaper rash.
- Application on wounds or ulcers.

Precautions

-This medication is for external use only. It should not be used on eyes or under an occlusive dressing. Notify your doctor if the condition being treated gets worse, or if burning, swelling or redness develops. Report any signs of local adverse reactions.

- The treated skin area should not be bandaged or otherwise covered or wrapped as to be occluded unless directed by your doctor.
- In case of bacterial infection, an antimicrobial treatment should be used.
- Using a topical corticosteroid in patients with skin atrophy, on large surface areas or in children may increase its systemic absorption. Pediatric patients may be more susceptible to topical corticosteroid-induced systemic toxicity than adults. Do not use for children without medical advice.
- You should avoid sources of infection or re-infection.
- This medication is to be used for the full prescribed treatment time, even though the symptoms may have improved.
- A rebound effect may occur after stopping the treatment. Corticosteroids may slow down cicatrization.
- Don't use this medication for any disorder other than for which it was prescribed or for longer than the prescribed time period.
- Do not increase the dose without consulting your doctor. More frequent applications may increase the risk of side effects without ameliorating the therapeutic effects.
- For athlete's foot, wear well-fitting and ventilated shoes and change shoes and socks at least once a day. If used over the inguinal region, you should wear loose-fitting clothing.
- Ask your doctor about the use of this medicine in case of pregnancy or lactation. Since its safe use during pregnancy and lactation has not been determined, this product should be used with caution in pregnant and nursing women.

Associations with other medications

Please inform your doctor if you are using any other medication. Do not put cosmetics or other skin products over the treated area unless directed by your physician. You should avoid preparations that may dry or irritate your skin. Other corticosteroid containing products should not be used with this cream without first talking to your doctor.

Adverse reactions

The short course of treatment with this medication limits the occurrence of adverse reactions. The following local adverse reactions are reported infrequently with this drug and may occur more frequently with the use of occlusive dressings. They include: paresthesia, maculopapular rash, edema, urticaria, secondary infection, erythema, stinging, blistering, peeling, pruritus, irritation, burning, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, striae, miliaria, and skin atrophy.

Children and patients with severe hepatic dysfunction are more susceptible to systemic side effects.

The use over large surface areas, on damaged skin or skin atrophy, prolonged use and the addition of occlusive dressings increase systemic absorption of topical corticosteroids and the risk of systemic side effects.

Storage

Store at controlled room temperature (up to 30°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don't use this medicine after this date.

Pack presentation

BETA-MICOTER cream, Clotrimazole 1% and betamethasone 0.05% (as betamethasone dipropionate), tube of 40 grams

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BETR/002

Manufactured by Mediphar Laboratories -Lebanon