

## BETA-MICOTER<sup>®</sup> 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 is a topical preparation containing:

Clotrimazole 1%

Betamethasone 0.05% (as betamethasone dipropionate)

Other ingredients: Vaseline, glycol palmito stearate, methyl paraben, propyl paraben, 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) and tinea corporis (fungal infection of the body) due to *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, and *Trichophyton rubrum*.

### **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 or tinea corporis 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 or tinea corporis 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 should not be used in case of hypersensitivity to any of the components, to other corticosteroids or to imidazoles.

### **Precautions**

- This medication is for external use only. Avoid contact with the eyes or the mouth.
- Don't use this medication for any disorder other than for which it was prescribed or for longer than the prescribed time period.
- This medication is to be used for the full prescribed treatment time, even though the symptoms may have improved.
- The treated skin area should not be bandaged or otherwise covered or wrapped as to be occluded unless directed by your doctor.
- You should avoid sources of infection or reinfection.
- 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 has not been determined, this product should not be used extensively on pregnant patients in large amounts, or for prolonged periods of time. Avoid the use of this drug during the first trimester of pregnancy.
- Notify your doctor if the condition being treated gets worse, or if burning, swelling or redness develops. Report any signs of local adverse reactions.
- Do not increase the dose without consulting your doctor. More frequent applications may increase the risk of side effects without ameliorating the therapeutic effects.
- Pediatric patients may be more susceptible to topical corticosteroid-induced systemic toxicity than adults. Do not use for children without medical advice. Do not use tight-fitting diapers on a child being treated in the diaper area, as it may constitute an occlusive dressing.

#### **Association 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, burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, edema, rash, erythema, stinging, peeling, urticaria, skin fissures, secondary infection and skin atrophy.

The use over large surface areas, 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

**Issue date: 06/2008**

**BETR/001**