

## PATIENT INFORMATION LEAFLET

### Read all of this leaflet carefully because it contains important information for you

This medicine is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use DAKTARIN® cream carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after *one week*.

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### DAKTARIN® Cream

Miconazole 20mg/g

#### 1. WHAT DAKTARIN CREAM CONTAINS

- The active substance is miconazole nitrate.
- The other ingredients are water, PEG-6 (and) PEG-32 (and) glycol stearate, oleoyl macroglycerides, liquid paraffin, benzoic acid, and butylated hydroxyanisole.

#### 2. WHAT DAKTARIN CREAM IS USED FOR

DAKTARIN is a medicine used for treating infection of the skin by fungi including yeasts.

DAKTARIN cream is used in infections of the scalp, the beard, the trunk, the feet and hands and the groin. It is also used for napkin rash in babies.

#### 3. BEFORE YOU USE DAKTARIN CREAM

- Wash your hands carefully after you have used DAKTARIN Cream, except if the treatment is for the hands.
- Keep a towel and a washcloth for your own use. In this way you **avoid infecting other people**.
- Regularly change clothing, which comes into contact with the infected skin in order to avoid re-infecting yourself.
- **Do not apply DAKTARIN Cream to the eyes.**

#### Do not use DAKTARIN CREAM:

- if you are hypersensitive (allergic) to *miconazole* or any of the other ingredients of DAKTARIN cream (see WHAT DAKTARIN CREAM CONTAINS).

#### Pregnancy and Breast-feeding

DAKTARIN cream is minimally absorbed into the body when applied on the skin, however, safety in pregnancy has not been demonstrated.

Safety has not been demonstrated in breastfeeding women.

If you are pregnant or breast feeding your baby while using this medicine, please consult your doctor, pharmacist or other health care professional for advice.

#### **Taking other medicines while using DAKTARIN CREAM:**

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of DAKTARIN cream with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

- Oral anticoagulants (blood thinning medication): Ask a doctor or pharmacist before use if you are taking an oral blood thinning medication, such as warfarin.
- The effects and side effects of some other drugs (e.g. oral hypoglycemics and phenytoin) when used with DAKTARIN cream, can be increased. Ask a doctor or pharmacist before use if you are taking other medications.

#### **4. HOW TO USE DAKTARIN CREAM**

Always use DAKTARIN cream exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with others.

For a successful treatment, **apply DAKTARIN cream every day**. Do not stop using the medicine for at least a further 10 to 14 days after all symptoms have disappeared. Depending on the type and extent of the infection, the treatment may last 2 to 6 weeks.

Wash the infected shin and dry it well. Rub DAKTARIN gently into the skin with your fingertips. Do not treat the infected skin alone. Apply the product to the area around it also.

Wash your hands carefully after applying the cream. This is particularly important to avoid transferring the germs of the infected skin to other parts of the body or to other people.

Recommended dosage: Apply to skin **twice a day**.

*To open the tube, unscrew the cap. Then pierce the seal of the tube by means of the pin on the top of the cap.*

#### **If you use more DAKTARIN cream than you should:**

When DAKTARIN cream is applied more frequently than prescribed, it may cause some redness, swelling or a burning sensation. In this case, it is sufficient to skip one or two applications and start again according to normal scheme.

Accidental swallowing of a small amount of DAKTARIN cream is normally harmless. However, to make sure that there are no problems, call your doctor.

#### Information for the doctor in case of overdose:

- In the event of accidental ingestion an appropriate method of gastric emptying may be used if considered appropriate. If the patient is also taking certain other medicines (e.g. warfarin, oral hypoglycemics, and phenytoin), their effects and side effects may be strengthened.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

#### **5. POSSIBLE SIDE EFFECTS**

In rare cases, redness, irritation, and/ or a mild burning or itching sensation may occur at the site where you applied the DAKTARIN cream. If this happens, it is usually sufficient to skip one or a few applications.

Hypersensitivity to DAKTARIN cream is very rare. It can be recognized by itching, redness, and shortness of breath, and/ or a swollen face following an application. In this case you should stop the treatment and consult your doctor or pharmacist.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

#### **6. STORING AND DISPOSING OF DAKTARIN CREAM**

Keep DAKTARIN cream at 25 °C or below.

This medicine can be kept for only a limited period. Do not use DAKTARIN cream after the date (month and year) printed after "EXP", even if it has been stored properly.

You are advised to return old medicine to your pharmacist.

Keep all medicines out of the reach and sight of children.

#### **7. PRESENTATION OF DAKTARIN CREAM**

DAKTARIN cream is supplied in tubes containing 30g of cream.

#### **8. IDENTIFICATION OF DAKTARIN CREAM**

A smooth, white cream, miscible with water.

#### **9. REGISTRATION NUMBER/ REFERENCE NUMBER**

G/13.9.2/106

Namibia Reg. No.: 90/13.9.2/00610

NS 1

Botswana Reg. No.: B9315365

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#### **10. NAME AND ADDRESS OF REGISTRATION HOLDER**



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