

DAKTARIN® (miconazole nitrate)

Cream Powder

For external use only



WHAT IS DAKTARIN® FOR?

DAKTARIN® Cream/Powder is a medicine for treating **infection of the skin by fungi including yeasts.**

DAKTARIN® Cream is used, for instance, in:

- infections of the scalp, the beard, the trunk, the feet and hands and the groin;
- diaper rash in babies.

DAKTARIN® Powder is used, for instance, in:

- infections between the fingers and toes or in the groin;
- diaper rash in babies.

DAKTARIN® Powder is also shaken in socks and shoes to prevent infection of the feet. Usually, DAKTARIN® Powder is combined with DAKTARIN® Cream or Lotion.



WHEN NOT TO USE DAKTARIN®

Do not use DAKTARIN® Cream/Powder if you know you are **hypersensitive** to it or to other similar antifungal medicines.

WHAT SPECIAL PRECAUTIONS SHOULD YOU TAKE?

DAKTARIN® can cause severe allergic reactions. You must be aware of the signs of an allergic reaction while you are taking DAKTARIN®. See 'UNDESIRE EFFECTS'.

Do not apply DAKTARIN® Cream/Powder to the eyes.

Wash your hands carefully after you have used DAKTARIN® Cream/Powder, 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.

Oral anticoagulants (blood thinning medication): Ask a doctor or pharmacist before use if you are taking an oral blood thinning medication, such as warfarin.

Other medications: The effects and side effects of some other prescription medications, when taken with miconazole, can be increased. Ask a doctor or pharmacist before use if you are taking other medications.

Avoid inhaling DAKTARIN® Powder.

DAKTARIN® Powder contains talc which can cause breathing problems. Apply the powder close to the body to avoid inhalation. When treating infants and children, carefully shake the powder into your baby's diaper or onto your hand and apply to the infected area. Keep the shaker out of reach of children.



Pregnancy and breast-feeding

DAKTARIN® Cream/Powder is minimally absorbed into the body when applied on the skin. It is not known whether the active ingredient is excreted in human breast milk. If you are pregnant or nursing a baby, ask your doctor if you should use DAKTARIN® Cream/Powder.



HOW TO USE DAKTARIN® AND HOW MUCH

For a successful treatment, **apply DAKTARIN® Cream and/or Powder every day**. Do not stop using the medicine until at least a week 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 skin and dry it well. Rub DAKTARIN® gently into the skin with your finger tips. Do not treat the infected skin alone. Apply the product to the area around it also.

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

- **If you are using the cream:**

- Apply DAKTARIN® Cream to the skin **twice a day**. If you are also using DAKTARIN® Powder at the same time, it suffices to apply the cream once a day and the powder once a day.
- To open the tube unscrew the cap. Then pierce the seal of the tube using the pin on the top of the cap.

- **If you are using the powder:**

- Apply DAKTARIN® Powder to the skin **twice a day**. If you are also using DAKTARIN® Cream at the same time, it suffices to apply the powder once a day and the cream once a

day.

- Shake some powder into your socks and shoes once a day to treat or prevent infections of the feet.



UNDESIRE D EFFECTS

DAKTARIN® Cream/Powder is usually well tolerated.

Severe allergic reactions have been reported with DAKTARIN®. The signs of a severe allergic reaction may include:

- A swollen face, lips, mouth, tongue or throat
- Difficulty swallowing or breathing
- Itchy rash (hives)

Stop taking DAKTARIN® and get emergency medical help straight away if you notice or suspect any of these side effects.

- Burning sensation of the skin
- Skin inflammation
- Light skin patches
- Problem where DAKTARIN® has been applied on the skin
- Burning feeling where DAKTARIN® has been on the skin
- Itching where DAKTARIN® has been on the skin
- Warm feeling where DAKTARIN® has been on the skin
- Redness of the skin
- Itching
- Allergic skin rash caused by contact with something on the skin
- Skin rash
- Hives

Do not hesitate to report any other undesired effects to your doctor or pharmacist.



OVERDOSE

When DAKTARIN® Cream/Powder 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 the normal scheme.

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

Accidental inhalation of large quantities of DAKTARIN® Powder may cause breathing difficulty. If this occurs, seek medical attention immediately.

Information for the doctor in case of overdose

If the patient is also taking certain other medicines (e.g., warfarin, oral hypoglycemics, and phenytoin), their effects and side effects may be strengthened.



HOW TO STORE DAKTARIN®

Store DAKTARIN® Cream at 25°C or below. Store DAKTARIN® Powder between 15 and 30°C (this is at a normal room temperature). Always keep the tube and shaker properly closed.

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

You are advised to return old medicines to your pharmacist.



WHAT IS IN DAKTARIN®?

DAKTARIN® Cream/Powder is a medicine for treating infection of the skin by fungi including yeasts.

The active ingredient in DAKTARIN® Cream/Powder is **miconazole nitrate**.

- **DAKTARIN® Cream** comes in tubes of 30 and 15 grams and contains 20 milligrams miconazole (nitrate) per gram.

The cream also contains other ingredients, namely: benzoic acid, butylated hydroxyanisole, liquid paraffin, oleoyl macroglycerides, PEG-6 (and) Peg-32 (and) glycol stearate, and water.

- **DAKTARIN® Powder** comes in shakers of 20 grams and contains 20 milligrams miconazole (nitrate) per gram.

The powder also contains other ingredients, namely: colloidal silicon dioxide, talc and zinc oxide.

BATCH RELEASER

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Turnhoutseweg 30
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Lusomedicamenta – Sociedade Tecnica Farmaceutica SA
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Quelez de Baixo
2730-055 Barcarena
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PRODUCT REGISTRANT

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What you should know about medicines...

Always inform your doctor or pharmacist if you are using other medicines because some drugs should not be taken together.

It is important that you use medicines correctly. That is, you should:

- always carefully read the full patient information leaflet;
- use medicines only for the purpose for which you were given the medicines;
- use medicines only in the prescribed amount;
- use medicines only for the prescribed amount of time.

Keep all medicines out of the reach of children.

Never allow others to use medicines recommended for you and never use medicines prescribed for others.

Keep all medicines in their original packaging and in a dry place (never in the bathroom, for example!).

Make a habit of returning unused or old medicines to your pharmacist.

If someone has taken an overdose of a medicine, call a doctor.

The information in this leaflet is limited. Please consult your doctor or pharmacist for further information if required.