

Daktarin®

2% w/w Cutaneous Powder

miconazole nitrate

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

This medicine is available without prescription. However you still need to take Daktarin Powder 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 contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please contact your doctor or pharmacist.

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1 What Daktarin Powder is and what it is used for

Daktarin Powder is a medicine which is used to treat infections of the skin which may appear on the hands, feet, outer ear, trunk or groin. It is also used to treat nappy rash. The powder contains miconazole nitrate which works by destroying both the fungus that causes the infection and some of the associated

bacteria which may also be present. The powder helps to dry the skin as well as treat the infection.

This medicine is for use in adults and children of all ages.

2 Before you take Daktarin Powder

This medicine is suitable for most adults and children but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

❗ Do not use Daktarin Powder

- If you are allergic to the active substance, other similar antifungal medicines or any of the other ingredients of this medicine (listed in section 6).

If any of these apply to you, **get advice from a doctor or pharmacist without using Daktarin Powder.**

❗ Take special care with Daktarin Powder

- Avoid contact with the eyes.
- If you experience any irritation or sensitivity to the powder, stop using this medicine.

❗ Taking other medicines

- Talk to your doctor or pharmacist if you are taking oral anticoagulants (drugs used to **thin the blood** such as warfarin).
- The effects and side-effects of some drugs may increase when co-administered with miconazole. These include:
 - sulphonylureas such as gliclazide and glibenclamide (tablets taken to control blood sugar)
 - phenytoin (medicine used to control epilepsy).

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

❗ Pregnancy and breast-feeding

- Ask your doctor or pharmacist for advice before using this medicine if you are pregnant or breast-feeding.

❗ Important information about some of the ingredients of Daktarin Powder

- This product contains talc. Do not breathe in the powder as this may cause irritation of the airways. This is especially important for children and infants.

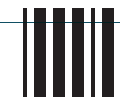
3 How to take Daktarin Powder

Check the table below to see how often to use.

- For cutaneous use only, which means it is applied directly to the affected area of skin.
- Wash the infected area and dry it well. As many skin conditions are contagious, you should keep a towel and flannel for your own use and not share it so that you do not infect anyone else.
- Sprinkle the powder onto the infected area and surrounding skin. It may be used on broken skin and is particularly useful where a drying effect is required. The powder can also be dusted inside socks, shoes and clothing which are in contact with the infected area.

turn over ►





- Wash your hands carefully after applying the powder to avoid spreading the infection to other parts of the body or to other people. Similarly, clothing which comes into contact with the infected areas, such as socks, should be washed and changed frequently.
- Do not use more often than the stated dose shown in the table.

i Adults and children of all ages

Age	Dose
Adults and children of all ages	Apply the powder to the infected skin once or twice a day (e.g. at night and in the morning).

- Continue treatment until the lesions have completely healed.
- If symptoms persist talk to your doctor.

! If anyone has swallowed this product

If anyone accidentally swallows Daktarin Powder, contact a doctor or your nearest Accident and Emergency department (Casualty), taking this leaflet and pack with you.

! If you forget to use the medicine

If you forget to use a dose, use the next dose when needed. **Do not** use a double dose.

4 Possible side-effects

Daktarin Powder can have side-effects, like all medicines, although these may not affect everyone.

If you experience any of the following, stop using the medicine and seek immediate medical help:

Very rare: may affect up to 1 in 10,000 people

- Severe allergic reactions including swelling of the face, lips, tongue or throat.
- Light headedness, generalised itch, wheezing or difficulty in breathing.

If you experience any of the following, stop using the medicine and talk to your doctor:

Very rare: may affect up to 1 in 10,000 people

- Allergic reactions such as a skin rash, itchiness, hives, swelling, redness or a burning feeling.
- hypersensitivity reactions (such as rash) at the application site. If this occurs stop using the medicine.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Daktarin Powder

This medicinal product does not require any special storage precautions.

Keep the product out of the sight and reach of children.

Do not use your medicine after the date shown as the expiry date on the packaging.

6 Further information

What's in this medicine?

The active ingredient in 1 g of Daktarin Powder is: Miconazole nitrate 20 mg.

Other ingredients are: Talc, zinc oxide and colloidal anhydrous silica.

What the medicine looks like

Daktarin Powder is a white powder in bottles of 20 g.

Product Authorisation Holder:

JNTL Consumer Health I (Ireland) Ltd.
Block 5, High Street, Tallaght, Dublin 24, Ireland.

Manufacturer:

Lusomedicamenta - Sociedade Técnica Farmacêutica S.A., Estrada Consiglieri Pedroso 69-B, Queluz de Baixo, 2730-055 Barcarena, Portugal or McGregor Cory Ltd, Middleton Road, Banbury OX16 8RS.

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