Package leaflet: Information for the user

Daktarin®
2% w/w Cream
miconazole nitrate

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if your symptoms persist or get worse, or if new symptoms occur.

What is in this leaflet

1. What Daktarin Cream is and what it is used for
2. What you need to know before you use Daktarin Cream
3. How to use Daktarin Cream
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1 What Daktarin Cream is and what it is used for

Daktarin 2% Cream is a medicine which is used in the treatment of fungal and associated bacterial infections of the skin. Skin infections may appear on the hands, feet, outer ear, trunk or groin and include athlete's foot, dhobie itch and intertrigo. Daktarin 2% Cream is also effective against infected nappy rash. The cream 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. It also has moisturising properties to help soothe cracked, red skin.

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

2 What you need to know before you use Daktarin Cream

Do not use Daktarin Cream
- If you are allergic to miconazole, other similar antifungal medicines or any of the other ingredients of this medicine (listed in section 6).
  If this applies to you, **get advice from a doctor or pharmacist without using Daktarin 2% Cream**.

Warnings and Precautions
- Avoid contact with the eyes.
- If you experience any irritation or sensitivity to the cream, stop using this medicine.
- Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings, etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.
- If you are taking oral anticoagulant agents such as warfarin, stop using Daktarin 2% w/w Cream immediately and seek advice from your doctor or pharmacist if you experience unexpected bleeding or bruising, nosebleeds, coughing up blood, blood in the urine, black tarry stools or coffee ground vomit during treatment with Daktarin 2 % w/w Cream. Close monitoring of International Normalized Ratio (INR) levels are required under the supervision of a healthcare professional during treatment with Daktarin 2% w/w Cream.

Other medicines and Daktarin 2% w/w Cream
- Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
  - Oral anticoagulant agents (drugs used to thin the blood), such as warfarin, may be affected by Daktarin 2% w/w Cream.
  - The effects and side-effects of some drugs may increase when co-administered with miconazole. These include:
- tablets taken to control blood sugar such as sulphonylureas including gliclazide and glibenclamide.
- phenytoin which is 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
- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Daktarin Cream contains:
- 2 mg of benzoic acid in each g of cream. Benzoic acid may cause local irritation. Benzoic acid may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- butylated hydroxyanisole which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

3 How to use Daktarin Cream

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Check the table below to see how often to use.
- Each tube of cream is sealed – use the cap to pierce the seal.
- For cutaneous use only, which means it is applied directly to the affected area of skin.
- Do not use more often than the stated dose shown in the table.

How to apply the cream
- 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.
- Apply the cream onto the infected area and surrounding skin.
- Wash your hands carefully after applying the cream 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.

Adults and children of all ages

Age	Dose
Adults and children of all ages	**Skin infections:** Apply the cream to the infected skin **twice** a day.

- Continue treatment until the lesions have completely healed.
- If symptoms persist or get worse, or if new symptoms occur, stop using Daktarin Cream and consult a doctor.
- If the powder is used with the cream, a once daily application of both formulations is recommended.
- The duration of therapy varies from 2 to 6 weeks depending on the localisation and severity of the lesion. Treatment should continue for at least one week after the disappearance of all signs and symptoms.

If anyone has swallowed this product
If anyone accidentally swallows Daktarin 2% Cream, contact a doctor or your nearest Accident and Emergency department (Casualty), taking this leaflet and pack with you.

If you forget to use Daktarin Cream
Do not use a double dose. Use the next dose when needed.

4 Possible side-effects
Like all medicines, this medicine can cause side-effects, although not everyone gets them.

If you experience any of the following, stop using the medicine and seek immediate medical help:
- 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:
Uncommon
- Skin burning sensation, skin inflammation or discolouration

Frequency Not known
- Allergic reactions such as 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, website: www.hpra.ie.
By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Daktarin Cream
Do not store above 25ºC.
Keep this medicine out of the sight and reach of children.
Do not use this medicine after the expiry date which is stated on the carton and label after 'Expiry'. The expiry date refers to the last day of that month.
Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information
What Daktarin Cream contains?
The active substance is miconazole nitrate 2% w/w (20 mg/g).
The other ingredients are: PEG-6, PEG-32 and glycol stearate, oleoyl macroglycerides, liquid paraffin, benzoic acid (E210), butylated hydroxyanisole (E320), purified water.

What Daktarin Cream looks like and contents of the pack.
Daktarin 2% Cream is a white cream available in tubes of 30 g.

Marketing Authorisation Holder and Manufacturer

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

Manufacturer: Janssen Pharmaceutica NV, Turnhoutseweg 30, B2340, Beerse, Belgium.
Or
JNTL Consumer Health (France) SAS, Domaine de Maigremont, Val de Reuil,2700, France

This leaflet was last revised in October 2026.

Daktarin is a registered trademark.