

Daktarin[®]

2% w/w Cream

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 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 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 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 Before you use Daktarin Cream

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 Cream

- 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 this applies to you, **get advice from a doctor or pharmacist without using Daktarin 2% Cream.**

Take special care with Daktarin Cream

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

Warnings and precautions

- 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.

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:

- 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

- 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 Cream

- This medicine 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).
- This medicine contains 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

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 talk to your 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 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 Cream 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 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 HPRAs 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 25°C.

Keep this medicine out of the sight and reach of children.

Do not use your 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 Further information

What's in this medicine?

The active ingredient in 1 g of Daktarin 2% Cream is miconazole nitrate 2%w/w (20 mg/g). Other ingredients are: PEG-6, PEG-32 and glycol stearate, oleoyl macroglycerides, liquid paraffin, benzoic acid (E210), butylated hydroxyanisole (E320), purified water.

What the medicine looks like

Daktarin 2% Cream is a white cream available in tubes of 30 g.

Product 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 revised

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