October 2026

Please note that there are currently 2 leaflets available for the Daktarin 2% Cream [PL 15513/0307].

It is the same product licence number for both leaflets *i.e.*, PL 15513/0307.

The information contained within each leaflet is identical apart from the manufacturer details and PIL presentation.

The leaflets are differentiated by leaflet dimensions, manufacturer, and the date of leaflet revision.

1. PIL 1 (pages 2-5)

    Manufacturer: "Janssen Pharmaceutica NV, Turnhoutseweg 30, B2340, Beerse, Belgium"

    PIL presentation: text

    or

2. PIL 2 (pages 6-7)

    Manufacturer: " JNTL Consumer Health (France) SAS Domaine de Maigremont, 27100 Val de Reuil, France"

    PIL presentation: mock-ups

This is a combined pdf of both leaflets.

Both these PILs are from different manufacturer as mentioned above and it will be inserted in carton as per its manufactured site. For the Beerse carton, the Beerse PIL (PIL 1) will be inserted and for the Val de Reuil site's carton, the Val de Reuil PIL (PIL 2) will be inserted.

Daktarin 2% Cream

Miconazole nitrate

- This medicine is used to treat fungal and bacterial infections of the skin and nails.
- This medicine is for use by adults and children of all ages.
- **Do not use this medicine:**
    - There are some people who should not use this medicine. *To find out if you are one of them See Section 2*
    - 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)
- **Speak to your doctor:**
    - If you suffer from any of the conditions mentioned in *Section 2*
    - If you are taking any **other medicines.** *See Section 2*
- **Follow the instructions on how to use this product carefully.** *See Section 3*

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

1 What the medicine is for

Daktarin 2% Cream is a medicine which is used in the treatment of fungal and associated bacterial infections of the skin and nails. 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 using this medicine

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.

X Do not use this medicine…

- 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.**

! Warnings and precautions

- Avoid contact with the eyes.
- Daktarin 2% Cream can cause severe allergic reactions. You must be aware of the signs of an allergic reaction while you are taking Daktarin 2% Cream. See 'Possible side-effects'

- If you are taking oral anticoagulant agents such as warfarin, stop using Daktarin 2% 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% Cream. Close monitoring of International Normalized Ratio (INR) levels are required under the supervision of a healthcare professional during treatment with Daktarin 2% Cream.

! Other medicines and Daktarin 2% Cream

Talk to your doctor, pharmacist or dentist 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% Cream.

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

! If you are pregnant or breast-feeding

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

! Some of the ingredients can cause problems

- This medicine contains butylated hydroxyanisole (E320) which may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.
- This medicine contains 2 mg of benzoic acid (E210) 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).

3 How to use this medicine

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 to the infected skin **twice a day.** **Nail infections:** Apply to the infected area **once or twice daily.**
• Continue treatment for **7 days (skin infections)** or **10 days (nail infections)** after all the symptoms have cleared to prevent them from coming back. • If symptoms persist or get worse, or if new symptoms occur, stop use and consult a doctor.	

! 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 2% Cream can have side-effects, like all medicines, although these don't affect everyone and are usually mild.

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

- A severe allergic reaction which may include:
  - Swelling of the face, lips, mouth, tongue or throat
  - Difficulty in swallowing or breathing
  - Itchy rash (hives)
- Skin burning sensation, application site reactions, application site irritation, application site burning, application site warmth, application site itchiness, skin inflammation, skin discolouration.

Other side-effects which may occur but it is unknown how often:

- Rash, skin irritation, itchiness or redness

If you experience any side-effects not included in this leaflet or are not sure about anything, **talk to your doctor or pharmacist.**

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side-effects you can help provide more information on the safety of this medicine.

5 Storing this medicine

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 label and carton 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 20 mg.
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 15 g.

Product Licence holder: McNeil Products Limited, 1Station Hill Square, Station Hill, Reading, RG1 1LN, UK.

Manufacturer: Janssen Pharmaceutica NV, Turnhoutseweg 30, B2340, Beerse, Belgium.

This leaflet was revised September 2026.

Daktarin is a registered trade mark.

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Daktarin® 2% CREAM

miconazole nitrate

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