

## Package leaflet: Information for the patient

### Daktarin AKTIV CREAM Miconazole nitrate 2.0% w/w Cream

- This medicine is used to treat Athlete's Foot.
- 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 c*
  - 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 c*
  - If you are taking any other medicines. *See Section 2 c*
- Follow the instructions on how to use this product carefully. *See Section 3 c*

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 Aktiv Cream is a medicine which is used to effectively treat and relieve Athlete's Foot. 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 caused by Athlete's Foot.

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.

### **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 Aktiv Cream.

### **Talk to your doctor or pharmacist if you are taking...**

- *Oral anticoagulants* (drugs used to thin the blood, such as *warfarin*).

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.

### **Special warnings about this medicine**

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

### **Some of the ingredients can cause problems**

- Benzoic acid (E210) may cause local irritation. It may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).
- Butylated hydroxyanisole (E320) may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

## 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
<b>Adults and children of all ages</b>	Apply the cream to the infected skin <b>twice a day</b> (e.g. at night and in the morning).
<ul style="list-style-type: none"> <li>■ Continue treatment for 7 days after all the symptoms have cleared to prevent them from coming back.</li> <li>■ If symptoms persist talk to your doctor.</li> </ul>	

### If anyone has swallowed this product

If anyone accidentally swallows Daktarin Aktiv 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 Aktiv 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](http://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 25°C.

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 Aktiv 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 Aktiv Cream is a white cream available in tubes of 15 g and 30 g.

### Product Licence holder:

McNeil Products Limited, 50 – 100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

### Manufacturer:

JNTL Consumer Health (France) SAS, Domaine de Maigremont, 27100 Val De Reuil, France.

**This leaflet was revised December 2022.**

Daktarin is a registered trade mark.

## 7 Facts about Athlete's Foot:

### **How do you catch Athlete's Foot?**

It's extremely infectious so anyone can pick it up, especially people sharing communal changing rooms and showers. Once the fungal spores have been transferred onto the feet, they thrive in the warm, moist areas between the toes. The skin soon becomes inflamed and itchy with flaking or cracking occurring. The infected flakes of skin are then shed onto the floor or into the socks and shoes by walking or friction. Someone else will be easily infected if they step on these flakes, or if they share towels or footwear with someone who has already got Athlete's Foot. What is more, even if you've already got rid of your Athlete's Foot, it's very easy to re-infect yourself. The

spores can live on or in your shoes or socks and if you don't change them regularly, or treat them with antifungal powders or spray powders, the Athlete's Foot soon returns.

### **How to prevent re-infection**

If you want to avoid the vicious circle of re-infection, here are a few helpful hints.

- Spray inside your shoes and socks with fungicidal powder before putting them on.
- Don't wear the same pair of shoes every day. This helps reduce the build-up of sweat which provides the moisture on which the fungus thrives.
- Avoid synthetic footwear. Choose cotton socks and leather shoes which allow your feet to breathe.
- Avoid sharing towels or footwear.
- Avoid walking barefoot in changing rooms.
- Dry thoroughly between your toes and keep toenails short as this reduces the number of places fungi can grow.