

Daktarin®

INTENSIV

CREAM

KETOCONAZOLE

- This medicine is used to treat Athlete's Foot and dhotie itch.
- This medicine is for use by adults.
- **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 have ever had a **bad reaction** to any of the ingredients. *For the list of ingredients. See 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 Intensiv Cream is a medicine which is used to treat skin infections which may appear on the feet (Athlete's Foot) or in the groin area (Dhotie Itch/tinea cruris). The cream rapidly relieves the itching which these fungal infections cause. It also provides long lasting protection from Athlete's Foot, as it will continue to work even after you have stopped using it.

The cream contains the active substance, ketoconazole, which works by destroying the fungi that cause the infection.

If you have Athlete's Foot, the skin between your toes will be red and itchy. Your skin may flake and crack and often the infection causes an unpleasant 'cheesy' smell. It is encouraged by moist, warm conditions and can be recognised by redness, irritation and itchiness between the toes.

Tinea cruris or Dhotie Itch is a fungal infection that occurs in the groin area and causes intense itching and inflammation (redness and soreness). In men, the skin of the

scrotum is often affected.
This medicine is for use in adults.

2 Before using this medicine

This medicine is suitable for most adults 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 have ever had a **bad reaction** to any of the ingredients.

If this applies to you, **get advice from a doctor or pharmacist without using Daktarin Intensiv Cream.**

! Talk to your doctor or pharmacist...

- If you recently used a cream, ointment or lotion on your skin infection that contains a corticosteroid (a group of medicines that work by reducing inflammation caused by a variety of skin conditions):
You should continue to apply a mild corticosteroid (such as hydrocortisone) cream, ointment or lotion in the morning whilst applying Daktarin Intensiv cream in the evening. The mild corticosteroid treatment can then be gradually stopped over a period of 2 to 3 weeks.
- If you are a diabetic you should visit your healthcare professional for regular check ups as diabetes can increase the risk of foot problems.

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

- You can use Daktarin Intensiv cream if you are pregnant or breast-feeding. Do not apply directly to the breast whilst breast-feeding.
- However, always ask your doctor or pharmacist for advice before using any medicine if you are pregnant or breast-feeding.

! Special warnings about this medicine

- Do not let the cream get into your eyes.

! Some of the ingredients can cause problems

- Propylene glycol may cause skin irritation.
- Cetyl alcohol and stearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

3 How to use this medicine

Check the tables below to see how often to use.

- Each tube of cream is sealed – unscrew the cap and use the cap to pierce the seal.
- For topical 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 (especially between the toes). 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 thinly 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.

! For Athletes Foot (infections between the toes)

Age	Dose
Adults	Rub the cream gently between the toes and surrounding area twice a day (morning and night) for 1 week.
	<ul style="list-style-type: none">■ If athlete's foot is more severe or extensive (e.g. affecting the sole or sides of the feet), continue to apply the cream to the affected areas for at least 2 to 3 days after signs of infection have cleared to prevent them coming back.■ If symptoms have not improved within 7 days talk to your doctor.

i For Dhobie Itch (Jock Itch)

Age	Dose
Adults	Rub the cream into the affected area once or twice daily.

- Continue treatment for at least 2 to 3 days after signs of infection have cleared. Treatment may be necessary for up to 6 weeks. You may feel relief from symptoms quickly but it is important that you continue to use the cream as described to prevent them from coming back.
- If symptoms have not improved within 4 weeks talk to your doctor.

! If anyone has swallowed this product

If anyone accidentally swallows Daktarin Intensiv 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 Intensiv 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:

Uncommon (less than 1 in 100 but more than 1 in 1000 people are affected)

- Severe allergic reactions including peeling or blistering of the skin.

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

Common (less than 1 in 10 but more than 1 in 100 people are affected)

- Itchiness or redness at the application site.
- A skin burning sensation may also occur.

Uncommon: (less than 1 in 100 but more than 1 in 1000 people are affected)

- Localised eczema (dermatitis), skin rash, sticky skin, irritation, prickling sensation, inflammation, discomfort, dryness, bleeding or other reactions at the application site.

Other effects:

- Urticaria also known as hives, where the skin looks blotchy with white raised wheals (bumps surrounded by redness).

If you experience any side-effects not included in this leaflet or are not sure about anything, **talk to your doctor or pharmacist**. Also you can help to make sure medicines remain as safe as possible by reporting any unwanted side-effects via the internet at www.mhra.gov.uk/yellowcard; alternatively you can call Freephone 0808 100 3352 (available between 10am – 2pm Monday to Friday) or fill in the paper form available from your local pharmacy.

5 Storing this medicine

Do not store above 25°C.

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

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

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Further information

What's in this medicine?

The active ingredient in 1 g of Daktarin Intensiv Cream is **prescription strength**: Ketoconazole 20 mg.

Other ingredients are: Propylene glycol, stearyl alcohol, cetyl alcohol, sorbitan stearate, polysorbate 60, polysorbate 80, isopropyl myristate, sodium sulphite (E221) and purified water.

What the medicine looks like

Daktarin Intensiv Cream is a white cream available in a 5 g, 15 g or 30 g tube. Not all pack sizes may be marketed.

Product Licence holder: McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

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

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.