

Daktarin® GOLD 2% Cream

ketoconazole

- This medicine is used to treat Athlete's Foot, dhotie itch and sweat rash skin infections.
- 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 Gold 2% Cream is a medicine which is used to treat skin infections which may appear on the feet (Athlete's Foot), in the groin area (Dhotie itch/tinea cruris) or between skin folds (Sweat Rash infected with a yeast infection 'thrush'). 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 and yeasts 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.

Candidal intertrigo or sweat rash which has been infected with a yeast infection ('thrush') is usually found under the breasts and where fleshy areas around the waist or under the armpits become

damp with perspiration between the deep folds of skin. The skin area becomes red and sore and it often looks like moisture is coming from the surface.

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 Gold 2% 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 Gold 2% cream in the evening. The mild corticosteroid treatment can then be gradually stopped over a period of 2 to 3 weeks.

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 Gold 2% 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 that follow 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. 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.

For skin infections of the trunk, groin, feet and hands, apply Daktarin Gold 2% Cream to the affected and immediate surrounding area once or twice a day.

Your doctor will tell you how often to use it and for how long. Depending on the type of infection, treatment may last 2 to 6 weeks.

The recommended dose is:

i For Athlete's foot (infections between the toes)

| Age | Dose |
|--------|---|
| Adults | Rub the cream gently between the toes and surrounding area once or twice a day (morning and night) for 4 to 6 weeks. Treatment may be necessary for up to 6 weeks. |
| | <ul style="list-style-type: none"> ■ Continue to apply the cream to the affected areas for a few days after signs of infection have cleared to prevent them coming back. ■ If symptoms have not improved within 4 weeks talk to your doctor. |

turn over ►

i For Dhoobie itch and Sweat Rash (Candidal Intertrigo)

| Age | Dose |
|--------|---|
| Adults | Rub the cream into the affected and surrounding area once or twice daily . |

- Continue treatment for a few days after signs of infection have cleared. Treatment may be necessary for up to 4 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.

A If anyone has swallowed this product

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

A 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 Gold 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:

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 people 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.

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 25°C.

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

Do not use your medicine after the date shown as the expiry date on the packaging. 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 Gold 2% Cream is: 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 Gold 2% Cream is a white cream available in a 15 g tube.

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

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

This leaflet was revised March 2019.

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.

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