

PATIENT INFORMATION LEAFLET

Daktarin Gold Ketoconazole 2% w/w

Information for people using Daktarin Gold

Before you start to use your Daktarin Gold, please read this leaflet carefully because it contains important information. If there is anything that you do not understand or if you need more information or advice, you should ask your pharmacist or doctor.

This leaflet applies only to Daktarin Gold. Please do not throw it away until you have completed the full course of your medicine. You may need to look at it again.

What is Daktarin Gold?

Your medicine is called Daktarin Gold and its active ingredient is ketoconazole. It comes in a 15 gram (g) tube.

Each gram of the cream contains 20 milligrams (mg) of ketoconazole. The cream also contains the following inactive ingredients: water, propylene glycol, stearyl alcohol, cetyl alcohol, sorbitan monostearate, Polysorbate 60, Polysorbate 80, isopropyl myristate and sodium sulphite (E221).

This product is one of a group of medicines called 'antifungals'. They are used to treat infections that are caused by fungi, including yeasts.

The UK Product Licence holder (PL number 0242/0107) for this medicine is: Janssen-Cilag Ltd, Saunderton, High Wycombe HP14 4HJ.

Daktarin Gold is made by Janssen Pharmaceutica NV, Turnhoutseweg 30, B2340 Beerse, Belgium or Laboratoires Janssen SA, Val de Reuil, France.

It is supplied by: Johnson & Johnson-MSD Consumer Pharmaceuticals, Enterprise House, Station Road, Loudwater, High Wycombe, Buckinghamshire HP10 9UF.

What is Daktarin Gold used for?

Daktarin Gold is used to treat skin infections which may appear on the feet (athlete's foot), in the groin area (Dhobie Itch/tinea cruris) or between skin folds (sweat rash infected with a yeast infection, 'thrush'). It destroys the fungus that causes the infection.

How to recognise fungal skin infections

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 Dhoobie 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 skin surface.

When should I not use Daktarin Gold?

Do not use this cream if you think that you may have had an allergic reaction to any of the ingredients, or a similar antifungal in the past. You may be allergic if you get a rash or itching where the infection is, which gets worse after you apply the cream.

If this applies to you, you should talk to your pharmacist or doctor before you use the cream. They will then decide whether this product is suitable for you.

Special Precautions

Do not put the cream into your eyes. You should only use it on your skin.

If you are or have recently been applying a 'potent corticosteroid' medicine (such as betamethasone, fluocinolone or triamcinolone) to your skin, speak to your doctor before you use Daktarin Gold because you should not use them at the same time or within two weeks of each other.

Pregnancy and breastfeeding

If you are pregnant or are planning to become pregnant, you should talk to your doctor before you use the cream. They will decide if you can use the cream. You can use Daktarin Gold whilst breastfeeding. It is inadvisable to apply directly to the breast while breastfeeding.

How do I use Daktarin Gold?

You should only use the cream on your skin

Every tube of the cream is sealed. To open:

- unscrew the cap
- use the cap to pierce the seal.

Every time you use the cream you should do the following:

- Wash the infected skin and dry it well. Many skin conditions are infectious so you should keep a towel and a flannel for your own use so that you do not infect anyone else.
- **For Athlete's Foot:** For mild athlete's foot: rub the cream gently between the toes and surrounding area twice a day (morning and night) for one week. If the athlete's foot is more severe or extensive (eg also 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 symptoms have cleared to prevent them coming back.
- **For Dhobie Itch and Sweat Rash (Candidal Intertrigo):** Rub the cream into the affected area once or twice daily for at least two to three days after symptoms have cleared. Treatment may be necessary for up to 6 weeks. You may feel relief from the symptoms quickly but it is important that you continue to use the cream as described to prevent them from coming back.
- Unless the infected skin is on your hands, wash your hands carefully to avoid spreading the infection to other parts of the body or to other people. Similarly, you should wash and change any clothing which comes into contact with the infected areas. Daktarin Gold is not greasy and should not stain clothes.
- If your symptoms have not improved after four weeks, you should talk to your doctor or pharmacist.

What happens if I swallow some Daktarin Gold?

It is not likely to harm you if you accidentally swallow Daktarin Gold but you should contact your doctor for advice.

What side effects may I suffer if I use Daktarin Gold?

Daktarin Gold does not usually cause side effects. Occasionally, you may get irritation or a burning sensation of the skin. If the irritation is very bad, stop using the cream and talk to your doctor.

In rare cases, if your skin is red and itchy after you have put the cream on, it may mean that you are allergic to the medicine (**see ‘When should I not use Daktarin Gold?’**). If this is the case, you should stop using it.

If your medicine affects you in any other way, you should tell your doctor or pharmacist.

How should I store Daktarin Gold?

Keep the product in a safe place where children cannot reach it.

Store the cream in its original packaging at 25°C or below.

Do not use the cream after the expiry date printed on the packaging.

Always return any medicine that you do not use to your pharmacist.

Date of preparation: April 2000

This text will appear on the back of the Daktarin Gold patient information leaflet.

What are fungal infections?

Fungal infections of the skin are not usually serious. However, they can be persistent and their symptoms are nearly always unpleasant and upsetting.

Symptoms include inflamed and broken skin, with itching and sometimes pain. Some infections slowly clear up by themselves whereas others are unlikely to clear without treatment. Re-infection is common.

Fungal infections are usually caused either by germs called dermatophytes, or by yeasts such as Candida. The skin, scalp and nails are most likely to be affected. Yeasts and dermatophytes grow well in moist, warm areas of the body such as:

- the groin;
- the anus and genital areas;
- the armpits;
- the area under the breasts;
- in the body folds of obese people; and
- between fingers and toes.

What is Tinea Cruris or ‘Dhobie Itch’?

It is a fungal infection which occurs around the groin and anus and genital regions. These areas become warm and moist, especially after playing sport, which allows fungal organisms to grow.

It can be recognised by redness, soreness and itching.

What is Candidal Intertrigo or Sweat Rash (‘Thrush’ of the skin folds)?

Sweating and rubbing together of moist skin parts (armpits, chest, between the legs etc) can produce tenderness, redness and swelling. This can lead to cracked skin allowing fungal and yeast infections to grow. Your skin will also be tender, red and swollen.

What is Athlete’s Foot?

It is a fungal infection that affects your feet, particularly between your toes.

How do you catch Athlete’s Foot?

It’s extremely infectious so anyone can pick it up, especially people who use shared changing rooms and showers.

When the fungal spores have been transferred onto the feet, they grow quickly in the warm, moist areas between the toes. The skin soon becomes inflamed, itchy and will flake or crack.

The infected flakes of skin then come off onto the floor or into the shoes.

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.

Even if you’ve already got rid of your athlete’s foot, it’s very easy to be infected again. The spores can live on or in your shoes or socks and if you don’t change them regularly, the athlete’s foot will return.

How to treat athlete’s foot, fungal infections of the groin and Candidal Intertrigo (sweat rash)?

You should start treatment as soon as you notice the first signs of infection. The fungus grows so fast that it is important to treat the affected area quickly and thoroughly. If the infection has caused badly cracked skin, you should use a cream which will soothe it.

If you are not sure, ask your pharmacist for advice.

How to prevent being infected again

If you want to help prevent yourself from being infected again, here are a few helpful hints.

- Don't wear the same pair of shoes or clothing every day. This helps reduce the build-up of sweat which provides the moisture on which the fungus thrives.
- Avoid wearing synthetic footwear. Wear 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 your toenails short. This reduces the number of places that fungi can grow.
- Try not to wear tight clothing when playing sport.
- Always try and let air get to tender, sore areas.