

Consumer Medicine Information

DAKTARIN[®]

Miconazole

20 mg/g Oral Gel

What is in this leaflet

This leaflet answers some of the common questions about DAKTARIN Oral Gel. It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

If you have any concerns about using DAKTARIN Oral Gel, ask your doctor or pharmacist. Your doctor and pharmacist have more information.

Keep this leaflet with your DAKTARIN Oral Gel. You may need to read it again.

What DAKTARIN Oral Gel is used for

DAKTARIN Oral Gel is used to treat infections of the mouth and throat (e.g. thrush).

DAKTARIN Oral Gel is an antifungal. These medicines work by treating infections caused by fungi, including yeast.

Your doctor may have prescribed DAKTARIN Oral Gel for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Before you use DAKTARIN Oral Gel

When you must not use it

Do not use DAKTARIN Oral Gel if you know you are allergic to any of the ingredients. (See the last section of this leaflet for a list of ingredients). Signs of allergy include a skin rash, itching, shortness of breath and/or a swollen face, lips, tongue or other parts of the body.

Do not use DAKTARIN Oral Gel if you have liver disease. DAKTARIN Oral Gel could make the symptoms of your liver disease worse.

Do not give DAKTARIN Oral Gel to an infant below the age of 6 months. The safety of this medicine in infants under 6 months of age has not been established.

Do not use DAKTARIN Oral Gel if the packaging is torn or shows signs of tampering. Do not use DAKTARIN Oral Gel beyond the expiry date (month and year) printed on the pack.

Do not use DAKTARIN Oral Gel if you are taking any of the following medicines because it may affect the way these medicines work:

- cisapride (used for digestive problems)
- simvastatin or lovastatin (used to lower cholesterol)
- certain medicines used to relieve anxiety or to help you sleep (oral midazolam or triazolam)
- pimozide (used to treat mental disorders)
- quinidine (used to treat irregular heart beats)

- astemizole and terfenadine (antihistamines).

Before you start to use it

Certain people must use DAKTARIN Oral Gel with caution. Ask your doctor for advice.

Tell your doctor or pharmacist if:

- you are pregnant or planning to become pregnant
- you are breast feeding or wish to breastfeed

Your doctor or pharmacist will advise whether you should use DAKTARIN Oral Gel or if you need to adjust the dose or adapt your treatment.

Other medicines:

Tell your doctor or pharmacist if you are taking any other medicines including medicines you can buy from a pharmacy, supermarket or health food shop.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- cisapride (used for digestive problems)
- terfenadine and astemizole (antihistamines)
- simvastatin or lovastatin (used to lower cholesterol)
- certain medicines to relieve anxiety or to help you sleep (midazolam by mouth or triazolam)
- pimozide (used to treat mental disorders)
- quinidine (used to treat irregular heartbeats).

If you have not told your doctor or pharmacist about any of the above, tell them before you start using or are given DAKTARIN Oral Gel.

There may be some other medicines that may cause problems if used together with DAKTARIN Oral Gel. So, make a point of telling your doctor or pharmacist which medicines you are taking at the moment, and before you start taking any new medicines. They will tell you which medicines should not be taken or what other measures (for example, a change of dose) are necessary.

Some medicines, which may be affected by DAKTARIN Oral Gel or may affect how well DAKTARIN Oral Gel works, are:

- medicines which slow blood clotting (warfarin or other anticoagulants) because bleeding or bruising may occur.
- certain medicines used to treat AIDS, such as saquinavir.
- certain medicines used to treat cancer, such as docetaxel.
- certain calcium channel blockers (used to treat high blood pressure or heart problems) such as verapamil and bepridil.
- cyclosporin, sirolimus or tacrolimus which are drugs usually given after an organ transplant to prevent organ transplant rejection.
- medicines taken by mouth for diabetes such as tolbutamide, tolazamide, glipizide and glimepiride.
- medicines for epilepsy (phenytoin or carbamazepine)
- alfentanil (used in surgery for pain relief and to help anaesthesia)
- sildenafil (used to treat male impotence)
- certain medicines for anxiety or to help you sleep (tranquillisers) such as triazolam.
- certain medicines used to treat tuberculosis
- methylprednisolone (given by injection to reduce inflammation).
- ergot alkaloids (used to treat migraine).
- disopyramide (used to treat unusual heart beat)

- halofantrine (used to treat malaria).

Using DAKTARIN Oral Gel

How much to use

Note: Use the spoon provided for accurate measurements.

Adults and children (2 years of age and older):

Half ($\frac{1}{2}$) a spoonful four times a day after food.

Infants (6-24 months):

One quarter ($\frac{1}{4}$) of a spoonful four times a day after food.

How to use it

Opening Instructions:

1. Unscrew the cap.
2. Reverse the cap and push it firmly into the neck of the tube to fully puncture the safety seal.

Follow these steps to ensure you use DAKTARIN Oral Gel properly:

After you have finished eating, drop the measured amount of gel onto the tongue and keep it in the mouth for as long as possible before swallowing. The gel is sticky to make sure it stays in the mouth as long as possible.

If you are giving the gel to infants and young children the measured dose should be given in small amounts placed in the front of the mouth. Do not give the whole amount at once. Do not put the gel in the back of the mouth. This is to make sure that the throat does not become blocked by the gel.

If you wear dentures, apply a thin layer of DAKTARIN Oral Gel directly on to the dentures in the evening and leave it on overnight. Make sure you wash your dentures before putting them back in, in the morning.

Wash and dry the measuring spoon after use.

Continue treatment for at least a week after symptoms have disappeared. This is to ensure that the treatment is complete.

If you forget to use it

If you forget to use DAKTARIN Oral Gel, do so as soon as you remember, and then go back to using it as you would normally.

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Do not use a double dose to make up for the one you missed.

If you have problems remembering when to use your medicine, ask your pharmacist for some hints.

If you have used too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre, or go to the Accident and Emergency Department at your nearest hospital immediately if you think you or anybody else has used too much DAKTARIN Oral Gel.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

You can contact the Poisons Information Centre by dialling (0800 764 766). This is a 24-hour a day service.

Information for the doctor in case of overdose

DAKTARIN Oral Gel has limited absorption and therefore systemic effects are not expected. There is no specific antidote.

While you are using DAKTARIN Oral Gel

Things you must do

- Avoid contact with eyes.

Things you must not do

- Do not use a medicine for any purpose other than for the purpose it has been recommended for you.
- Do not use more than the recommended amount.
- Do not give this medicine to anyone else even if their symptoms seem similar to yours.

Side Effects

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

DAKTARIN Oral Gel may have some unwanted side effects in a few people, even though it is usually well tolerated at the recommended dose.

Tell your doctor if any of the following symptoms happen and they worry you: nausea, vomiting, diarrhoea, loss of appetite, generally feeling unwell and chills.

Tell your doctor immediately if you notice any of the following: yellowing of the skin and eyes, fever, dark coloured urine, severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

Tell your doctor immediately and do not take your next dose of DAKTARIN Oral Gel if you experience: signs of allergy such as skin rash, reddening, blisters or itching, swelling of the face, lips or other parts of the body, shortness of breath or wheezing.

Other side effects not listed above may also occur in some people. Do not hesitate to report any other side effects to your doctor or pharmacist.

After using DAKTARIN Oral Gel

Storage

- Keep your DAKTARIN Oral Gel in a cool dry place where the temperature stays below 30°C.
- Do not store DAKTARIN Oral Gel or any other medicine in the bathroom or near a sink. Heat and dampness can destroy some medicines.
- Keep your medicines where young children cannot reach them. A locked cupboard at least one and a half metres (1.5m) above the ground is a good place to store medicines.

Disposal

Once you have finished using your DAKTARIN Oral Gel or the medicine has passed its expiry date, ask your pharmacist what you should do with any which may be left over.

Product Description

What it looks like

DAKTARIN Oral Gel is a white, jelly-like substance with an orange flavour. It comes in a tube size of 15 and 40 grams of the gel. The tube and a 5 mL measuring spoon are included in the carton.

Ingredients

Each gram of DAKTARIN Oral Gel contains:

- 20 milligrams of miconazole as the active ingredient
- glycerol, purified water, potato starch, ethanol, polysorbate 20, sodium saccharin, cocoa flavour and orange flavour as the inactive ingredients.

Sponsor

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