

PACKAGE LEAFLET: INFORMATION FOR THE USER

Daktarin[®] oral gel

Miconazole

Daktarin is a registered trademark

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If you get side effects and they become serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

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1. What Daktarin oral gel is and what it is used for

Daktarin oral gel is a medicine which is used to treat fungal infections of the mouth, throat and gullet. The gel contains miconazole which works by destroying the fungus that is present.

This medicine is for use in adults and children aged 4 months and over.

2. Before you use Daktarin oral gel

Do not use Daktarin oral gel:

- If you are allergic to miconazole, any of the other ingredients of this medicine (listed in section 6) or to other similar antifungal medicines
- If you suffer from liver problems
- If it is for an infant under 4 months of age because of risk of choking.

Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using Daktarin oral gel.

Take special care with Daktarin oral gel

Daktarin oral gel is sticky. This ensures that it stays in the mouth for as long as possible. If you are giving the gel to a child or infant, make sure that the gel does not close off the child's or infant's throat as they could choke on it. You should place the gel at the front of the mouth – never put it at the back of the throat.

If your infant is being treated with Daktarin oral gel, and you are breast-feeding, do not apply the gel to your nipple in order to give the gel to your infant.

Blood tests

If you are also taking medicines to thin the blood (anticoagulants, such as warfarin) or if you are taking phenytoin (a medicine for epilepsy), your doctor may want to check the level of the medicines in your body by testing your blood.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

In particular, do not take this medicine and tell your doctor if you are taking any of the following medicines:

- Medicines for hay fever or allergy called terfenadine, astemizole or mizolastine
- Cisapride – for digestive problems
- Medicines to lower cholesterol called lovastatin or simvastatin
- Midazolam (by mouth) or triazolam - for anxiety or to help you sleep
- Pimozide or sertindole - for conditions affecting thoughts, feelings and behaviour
- Medicines for an irregular heart beat called quinidine or dofetilide
- Ergotamine - used to treat migraine.

Do not start using Daktarin oral gel and tell your doctor if you are taking any of the above.

Tell your doctor or dentist before taking, or if you are already taking, any of the following medicines:

- Medicines to thin the blood (anticoagulants) such as warfarin.
- Medicines for HIV infection such as saquinivir. They are called ‘antiviral protease inhibitors’
- Medicines used in the treatment of cancer such as busulfan, docetaxel and a group of medicines known as ‘vinca alkaloids’
- Medicines that act on the heart and blood vessels called ‘calcium channel-blockers’ such as dihydropyridines and verapamil
- Medicines that are usually given after an organ transplant called cyclosporin, tacrolimus or rapamycin. Another name for rapamycin is sirolimus
- Medicines for epilepsy called phenytoin or carbamazepine
- Alfentanil - for pain
- Medicines used for anxiety or to help you sleep (tranquillisers), such as buspirone, alprazolam or brotizolam
- Midazolam - to help you relax or sleep when given into a vein
- Rifabutin - for tuberculosis
- Methylprednisolone - for inflammation (given by mouth or injection)
- Ebastine - for allergy
- Reboxetine - for depression
- Sulphonylureas such as chlorpropamide and glibenclamide (medicines for diabetes taken by mouth)
- Sildenafil – for erection problems

- Trimetrexate – for a type of pneumonia

Tell your doctor or dentist before taking, or if you are already taking any of the above. They may need to alter your treatment.

Pregnancy and breast-feeding

Please tell your doctor before using Daktarin oral gel if you are pregnant, think you may be pregnant or might become pregnant.

You may still be able to use Daktarin oral gel if your doctor thinks you need to.

Talk to your doctor before using this medicine if you are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

Daktarin oral gel is not likely to affect you being able to drive or use any tools or machines.

Important information about some of the ingredients of Daktarin oral gel

- Daktarin oral gel contains 0.00785 g of alcohol (ethanol) in each 1 g which is equivalent to 0.00785 mg/mg (0.785 % w/w). The amount in 1 g is equivalent to less than 1 mL beer or 1 mL wine.
The small amount of alcohol in this medicine will not have any noticeable effects.
- Daktarin oral gel contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use Daktarin oral gel

Always use Daktarin oral gel exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How to apply the gel

- Each tube of the gel is sealed - use the cap to pierce the seal
- For oral use only
- Keep the gel in the mouth as long as possible. Do not swallow it straight away
- If the infection is just in the mouth, apply directly to the affected area with a clean finger
- If you are wearing dentures, remove them at bedtime and rub them with the gel. This helps stop your dentures becoming infected too
- Do not use more than the stated dose
- Use after meals
- If you are giving the gel to a child or infant aged 4 months or over, make sure that the gel does not become a **choking hazard** by making sure you **place the gel at the front of the mouth**

How much gel to use

Your doctor will tell you how much Daktarin oral gel to take and for how long you should take it. Your doctor will probably suggest the following treatment course:

Infections of the mouth and throat:

- **Adults and Children over 2 years:** 2.5 ml (half a 5ml spoonful) of gel applied four times a day after food.
- **Infants 4 months - 2 years:** 1.25 ml (one quarter of a 5 ml spoonful) of gel applied four times a day after food. Each application should be divided into smaller portions.

If the infant is 4-6 months old, and is premature or has slow development, check with your doctor before using this medicine

If symptoms persist, talk to your doctor.

When to stop using Daktarin oral gel

Keep using the gel for at least a week after all the symptoms have gone away. This will stop the symptoms from coming back.

If you forget a dose

- Do not apply the missed dose of gel
- Apply the next dose of gel as usual and keep using it as your doctor has told you
- Do not use a double dose of gel to make up for a missed dose

If you use more Daktarin oral gel than you should

If you use more Daktarin oral gel than you were told to or if someone else has taken any, talk to a doctor or go to the nearest hospital casualty department straight away.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Daktarin oral gel can cause side effects, although not everybody gets them.

Stop using Daktarin oral gel and tell your doctor straight away if you notice the following. You may need medical treatment.

- Sudden swelling of the face, lips, tongue or throat; difficulty swallowing; hives (also known as nettle rash or urticaria) and breathing difficulties (angioedema, anaphylactic reactions); severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction.
- Severe skin disorders with peeling and/or rashes with small pus-containing pimples (with a fever) or blistering of your skin, mouth, eyes and genitals (toxic epidermal necrolysis or Stevens-Johnson Syndrome)
- Light headedness, generalised itch, wheezing or difficulty breathing.
- If you are taking medicines to thin the blood (anticoagulants), such as warfarin: unexpected bleeding or bruising, nosebleeds, coughing up blood, blood in the urine, black tarry stools or coffee ground vomit.

Other side effects which may occur:

Common (affects 1 to 10 users in 100)

- Dry mouth

- Feeling sick (nausea)
- Being sick (vomiting)
- Mouth discomfort
- Regurgitation
- Product tastes abnormal

Uncommon (affects 1 to 10 users in 1,000)

- Loss or abnormal sense of taste

The following side effects were also seen in a small number of patients

- Choking
- Diarrhoea
- Inflammation of the liver (hepatitis)
- Sore mouth
- Tongue discolouration
- Rash with pus filled pimples/blisters (acute generalised exanthematous pustulosis)

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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Daktarin oral gel

Keep out of the reach and sight of children.

Store the gel in its original packaging. Store below 30°C.

Shelf life after first opening is 3 months.

Do not use Daktarin oral gel after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

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 protect the environment.

6. Further information

The active substance in Daktarin oral gel is miconazole. Each gram (g) of Daktarin oral gel contains 20 milligrams (mg) of miconazole.

The other ingredients are pregelatinised potato starch, alcohol, polysorbate 20 (E432), sodium saccharin, cocoa flavour, orange flavour, glycerol and water.

What Daktarin oral gel looks like and contents of the pack

Daktarin oral gel comes in a tube containing 40 g of a white, sugar free gel with an orange flavour. A 5 ml plastic spoon, marked with a 2.5 ml graduation is provided.

Marketing Authorization Holder:

Janssen-Cilag NV Antwerpseweg 15-17 2340 Beerse, Belgium

Manufacturer

Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

This leaflet was last approved in 22 January 2021

THIS IS A MEDICAMENT

- Medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament. The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children

Council of Arab Health Ministers, Union of Arab Pharmacists