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 prevent and treat fungal and bacterial infections of the mouth, throat, gullet, stomach or gut. The gel contains miconazole which works by destroying the fungus and associated bacteria which may be 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 anything in Daktarin oral gel (listed in section 6 below)
- 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.
Blood tests
If you are also taking medicines to thin the blood (anticoagulants) or 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 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 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 small amounts of ethanol (alcohol), less than 100 mg per dose.

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 and 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:

• Adults: One to two 5 ml spoonfuls of gel four times a day (such as after meals and at bedtime)
• Children aged 6 years and over: One 5 ml spoonful of gel four times a day
• Children aged 2-6 years: One 5 ml spoonful of gel twice a day
• Infants 4 months - 2 years: Half a 5 ml spoonful of gel twice a day. 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 2 days 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. Hives (also known as nettle rash or urticaria), severe irritation, reddening or blistering of your skin. These may be signs of a severe allergic reaction.
- Blistering of your skin, mouth, eyes and genitals
- Light headedness, generalised itch, wheezing or difficulty breathing

**Other side effects which may occur:**

**Common** (affects less than 1 in 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
• Serious Skin reaction, with a widespread rash and peeling of the skin and blistering of the mouth, eye and genitals (toxic epidermal necrolysis or Stevens-Johnson Syndrome)

If you get any of these side effects, or other side effects not listed in this leaflet, tell your doctor or pharmacist straight away.

5. How to store Daktarin oral gel

Keep out of the reach and sight of children.

Store the gel in its original packaging. Do not store above 30°C.

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 80 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.

The product licence is held by:
JANSSEN-CILAG LTD, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire HP12 4EG, UK

Daktarin oral gel is made by:
Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium
OR
McGregor Cory Ltd, Middleton Close, Banbury, OX16 8RS, UK

For information in large print, tape, CD or Braille, telephone 0800 7318450.

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