

Package leaflet: Information for the user

Daktarin® 20 mg/g oral gel

Miconazole

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Daktarin Oral Gel is and what it is used for
2. What you need to know before you use Daktarin Oral Gel
3. How to use Daktarin Oral Gel
4. Possible side effects
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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 superficial fungal infections of the mouth and throat. The gel contains miconazole which works by destroying the fungus.

Daktarin Oral Gel may also be used to prevent and treat fungal infections of the gastrointestinal tract, in children and adults who have difficulty swallowing tablets.

This medicine is for adults, children and infants aged 4 months and over.

2 What you need to know before you use Daktarin Oral Gel

This medicine is suitable for most adults and children but a few people should not use it. If you are in any doubt, talk to your doctor or pharmacist.

Do not use Daktarin Oral Gel

- If you are allergic to the active substance, other similar antifungal medicines or any of the other ingredients of this medicines (listed in section 6).
- If you suffer from liver dysfunction.
- If it is for an infant under 4 months of age because of the risk of choking.
- The lower age limit should be increased to 5 - 6 months of age for infants who are premature or have slow development.
- In infants who have difficulty swallowing.
- If you are taking any of the following medicines:
 - *Warfarin* (a drug used to thin the blood), unless prescribed by your doctor.
 - *Terfenadine*, *astemizole* or *mizolastine* (drugs found in hayfever or antihistamine products).
 - *Cisapride* (a drug used to treat certain digestive problems).
 - *Simvastatin* and *lovastatin* (types of drugs used to treat high cholesterol).
 - Tranquillisers such as *midazolam* (taken by mouth) and *triazolam* (drugs used to treat anxiety or to help you sleep).
 - *Pimozide* and *Sertindole* (drugs used for mood disorders).
 - *Quinidine* and *dofetilide* (type of drugs used to treat irregular heart beat).

- Certain drugs used to treat migraine, such as ergot *alkaloids*.

If any of these apply to you, get advice from a doctor or pharmacist without using Daktarin Oral Gel.

If you are not sure about any of the medicines you are taking, show the tube or pack to your pharmacist.

Warnings and precautions

- Stop using Daktarin Oral Gel immediately and seek advice from your doctor or pharmacist if you experience unexpected bleeding or bruising, nosebleeds, coughing up blood, blood in the urine, black tarry stools or coffee ground vomit.
- Close monitoring of INR levels are required if you are taking warfarin under the supervision of a doctor.
- 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 you are breast-feeding, never apply the gel to your nipple to treat the baby.
- If the infant is over 4 months old, and is premature or has slow development, check with your doctor before using this medicine.

Other medicines and Daktarin Oral Gel

Talk to your doctor, pharmacist or dentist if you are taking, have recently taken or might take any other medicines.

- *Oral anticoagulants* (drugs used to thin the blood, such as *warfarin*).
- HIV Protease Inhibitors such as *saquinavir* (used to treat HIV).
- Certain antineoplastic agents such as *vinca alkaloids*, *busulfan* and *docetaxel* (used to treat cancer).
- Certain calcium channel blockers such as *dihydropyridines* and *verapamil* (used to treat hypertension, angina and arrhythmias).
- Certain medicines that act on the heart and blood vessels such as cilostazol or disopyramide.
- Certain immunosuppressive agents such as *cyclosporin*, *tacrolimus*, *sirolimus* (= *rapamycin*) (used to treat autoimmune disorders).
- The effects and side-effects of some drugs may increase when co-administered with miconazole. These include:
 - sulphonylureas such as gliclazide and glibenclamide (tablets taken to control blood sugar)
 - phenytoin (medicine used to control epilepsy).
 - Other medicines such as *phenytoin*, *carbamazepine*, *buspirone*, *alfentanil*, *sildenafil*, *alprazolam*, *brotizolam*, *midazolam IV*, *rifabutin*, *methylprednisolone*, *trimetrexate*, *ebastine* and *reboxetine*.

If you are not sure about any of the medicines you are taking, show the bottle or pack to your pharmacist.

Daktarin Oral Gel with food and drink

Daktarin Oral Gel should be used after meals.

Pregnancy and breast-feeding

- Ask your doctor or pharmacist for advice before using this medicine if you are pregnant, think you are pregnant, planning to become pregnant or breast-feeding.

Some of the ingredients can cause problems

- This medicine contains less than 1 mmol sodium (23 mg) per gram, that is to say essentially 'sodium-free'.
- This medicine contains 7.58 mg/g of alcohol (ethanol) which is equivalent to 6.064 mg/ml (15.1 mg/2.5 ml dose). The amount in each 2.5 ml dose 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.

3 How to use Daktarin Oral Gel

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Check the tables below to see how much medicine to use.

- Each tube of the gel is sealed - use the cap to pierce the seal.
- For oral use only.
- Do not use more than the stated dose shown in the table.
- Use after meals.

How to apply the gel.

- Apply directly to the affected area with a clean finger. Try to keep the gel in contact with the affected area for as long as possible.
- For oral candidosis, dentures should be removed at bedtime and brushed with the gel. This will help to prevent your dentures becoming infected as well.
- If you are giving the gel to a child or infant, make sure that the gel does not become a choking hazard by dividing each application into smaller portions - never put the whole amount in the mouth of the child at once. Make sure you place the gel at the front of the mouth.
- If the infant is over 4 months old, and is premature or has slow development, check with your doctor before using this medicine.

Infants under 4 months old

Do not use in infants less than 4 months old.

Infants and children 4 months - 2 years old

Age	Dose
Infants and children 4 months - 2 years old	Apply 1.25ml (¼ of 5ml spoon) four times a day.
<ul style="list-style-type: none">■ When giving to a child or infant, place the gel at the front of the mouth - never put it at the back of the throat.■ Continue treatment for at least a week after all the symptoms have cleared.■ If the infant is over 4 months old, and is premature or has slow development, check with your doctor before using this medicine.■ If symptoms persist talk to your doctor.	

Adults and children aged 2 years and over

Age	Dose
Adults and children aged 2 years and over	Apply 2.5ml (½ of 5ml spoon) four times a day.
<ul style="list-style-type: none">■ Continue treatment for at least a week after all the symptoms have cleared.■ If symptoms persist talk to your doctor.	

Adults and children 4 months - stomach infections

The dosage is 20mg per kg body weight per day, administered in four individual doses.	
<ul style="list-style-type: none">■ The daily dose should not exceed 250mg (10ml oral gel) four times a day.■ The treatment should be continued for at least a week after the symptoms have disappeared.	

If anyone has used too much of this product

If anyone accidentally uses too much of Daktarin Oral Gel, or if large quantities of the gel are accidentally swallowed, contact a doctor or your nearest Accident Emergency Department (Casualty) taking this leaflet.

If you forget to take Daktarin Oral Gel

If you forget to take a dose, take the next dose when needed. Do not take a double dose.

4 Possible side-effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If Daktarin obstructs the throat, infants and children may choke.

If you experience any of the following side effects, stop taking Daktarin Oral Gel and contact your doctor immediately:

- Swelling of face, tongue or throat; difficulty swallowing; hives and breathing difficulties (angioedema, anaphylactic reactions, frequency not known).

- any symptoms of Toxic Epidermal Necrolysis (serious illness with blistering of the skin) or Stevens-Johnson

Syndrome (serious illness with blistering of the skin, mouth, eyes and genitals) or Drug Reaction with Eosinophilia and Systemic Symptoms (grouped symptoms including rash, fever and internal effects with abnormal blood test results)

- Effects on blood clotting in patients taking warfarin (a medicine to thin the blood) which can cause unexpected bleeding or bruising, nosebleeds, coughing up blood, blood in the urine, black tarry stools or coffee ground vomit.

If you experience any symptoms of hypersensitivity (such as hives or rash) you should seek immediate medical attention.

If you experience any of the following, stop using the medicine and talk to your doctor or pharmacist:

Common: may affect up to 1 in 10 people

- Nausea, vomiting or regurgitation

- Dry mouth and oral discomfort

- Taste disturbance

Uncommon: may affect up to 1 in 100 people

- Dysgeusia (taste distortion)

Not known: frequency cannot be estimated from the available data

- Rash with pus filled pimples/blisters (acute generalised exanthematous pustulosis)

- Light headedness, generalised itch, wheezing or difficulty breathing.

- Inflammation of the liver (hepatitis) may occur.

- Tongue discolouration

- Stomatitis, an inflammation of the lining of the mouth.

- Diarrhoea

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 HPRA Pharmacovigilance, website: www.hpra.ie.

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

5 How to store Daktarin Oral Gel

Do not store above 30°C.

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

Do not use this medicine after the expiry date which is stated on the label and carton after 'Expiry'. 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 Contents of the pack and other information

What Daktarin Oral Gel contains

The active ingredient in 1 g of Daktarin Oral Gel is: Miconazole 20 mg.

Other ingredients are: Purified water, pregelatinised potato starch, ethanol (alcohol), polysorbate 20, sodium saccharin, cocoa flavour, orange flavour, and glycerol.

What Daktarin Oral Gel looks like and contents of the pack

Daktarin Oral Gel is a white sugar free gel with an orange flavour available in tubes of 30g and 40g.

Not all pack sizes may be marketed.

Product Licence holder: JNTL Consumer Health I (Ireland) Limited, Block 5, High Street, Tallaght, Dublin 24, Ireland

Manufacturer: Janssen Pharmaceutica NV, Turnhoutseweg 30, B-2340 Beerse, Belgium.

or

Pharmapac UK Ltd, Bidston, Wirral, CH41 7EL.

or

McGregor Cory Ltd, Exel, Middleton Close, Banbury, Oxon, OX16 4RS, UK.

This leaflet was revised

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