

## Daktarin® 20 mg/g oral gel

### miconazole

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However you still need to take Daktarin Oral Gel carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects get serious or if you notice any side effects not listed in this leaflet, please contact 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 and throat. The gel contains miconazole which works by destroying the fungus and associated bacteria which may be present.

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

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

## 2 Before you take 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.

### **X** Do not use Daktarin Oral Gel

- If you have ever had an allergic reaction to any of the ingredients - please see section 6 for a list of ingredients.
- 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**:
  - 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.

### **!** 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 the infant is over 4 months old, and is premature or has slow development, check with your doctor before using this medicine.

### **!** Taking 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.

### **!** Taking 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.

### **!** 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 take Daktarin Oral Gel

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.

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### 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.

#### **i** Infants under 4 months old

Do not use in infants less than 4 months old.

#### **i** 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.

- 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.

#### **i** 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.

- Continue treatment for up to 2 days after all the symptoms have cleared.
- If symptoms persist talk to your doctor.

#### **i** Adults and children 4 months - stomach infections

**The dosage is 20mg per kg body weight per day, administered in four individual doses.**

- 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 the medicine

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

## 4 Possible side-effects

Daktarin Oral Gel can have side-effects, like all medicines, although these may not affect everyone. If Daktarin obstructs the throat, infants and children may choke.

If you experience 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) stop taking the medicine and contact your doctor or pharmacist immediately.

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:

**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

- 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

If you experience any side-effects not included in this leaflet or are not sure about anything, **talk to your doctor or pharmacist.**

## 5 How to store Daktarin Oral Gel

Do not store above 30°C.

Keep the product out of the reach and sight of children.

Do not use after the date shown as the expiry date on the packaging.

## 6 Further information

#### What's in this medicine?

**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 the medicine looks like

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

#### Product Licence holder:

McNeil Healthcare (Ireland) Limited  
Airtown Road  
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 September 2013**

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IE - AW\_86765