

Daktarin® Sugar Free 2% ORAL GEL

miconazole

- This medicine is used to prevent and treat fungal and bacterial infections of the mouth and throat.
- This medicine is for use by adults, infants and children aged 4 months and over.
- **Do not take this medicine:**
 - Some people should not use this medicine. To find out if you are one of them See Section 2 ▶
 - If you have ever had a **bad reaction** to any of the ingredients. See Section 6 ▶
- **Speak to your doctor:**
 - If you suffer from any of the **conditions** mentioned in section 2. See Section 2 ▶
 - If you are taking any **other medicines**. See Section 2 ▶
- **Follow the dosage instructions carefully.** Children of different ages and adults need different amounts. These are shown in the dosage table. See Section 3 ▶
- If you are giving the gel to a child or infant, ensure that the gel does not become a **choking hazard** by making sure you **place the gel at the front of the mouth**. See Section 3 ▶

Now read this whole leaflet carefully before you use this medicine. Keep the leaflet: you might need it again.

1 What the medicine is for

Daktarin Sugar free 2% 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.

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

2 Before using this medicine

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 this medicine...

- If you have ever had a **bad reaction** to any of the ingredients.
- If you suffer from **liver dysfunction**.
- If it is for an infant under **4 months** of age because of the risk of choking.
- 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 Sugar free 2% Oral Gel**.

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

! Talk to your doctor or pharmacist if you are taking...

- *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**).
- *Sulphonylureas* such as *chlorpropamide* and *glibenclamide* (medicines for **diabetes** taken by mouth).
- **Other medicines** such as *phenytoin*, *carbamazepine*, *buspirone*, *alfentanil*, *sildenafil*, *alprazolam*, *brotizolam*, *midazolam* (by injection), *rifabutin*, *methylprednisolone*, *trimetrexate*, *ebastine* and *reboksetine*.

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

! If you are pregnant or 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.

! Special warnings about this medicine

- Daktarin Sugar free 2% 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 4 - 6 months old, and is premature or has slow development, check with your doctor before using this medicine.

! Some of the ingredients can cause problems

- Daktarin Sugar free 2% Oral Gel contains small amounts of ethanol (alcohol), less than 100 mg per dose.

turn over ▶





3 How to use this medicine

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.
- If you are wearing dentures, you should preferably remove them at bedtime and brush them with the gel. This will help 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 4 - 6 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 - 6 years old

Age	Dose
Infants and children 4 months - 6 years old	Apply a small amount to the affected area twice 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 up to 2 days after all the symptoms have cleared. ■ 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. 	

i Adults and children aged 6 years and over

Age	Dose
Adults and children aged 6 years and over	Apply a small amount to the affected area 4 times a day .
<ul style="list-style-type: none"> ■ Continue treatment for up to 2 days after all the symptoms have cleared. ■ If symptoms persist talk to your doctor. 	

! If anyone has used too much of this product

If anyone accidentally uses too much of Daktarin Sugar free 2% 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 Sugar free 2% Oral Gel can have side-effects, like all medicines, although these don't affect everyone and are usually mild. If Daktarin obstructs the throat, infants and children may choke.

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

- Very rarely: (less than 1 in 10,000 people are affected).
- Severe allergic reactions including swelling of the face, lips, tongue or throat.
 - Light headedness, generalised itch, wheezing or difficulty breathing.
 - Skin rashes which may be severe and include blistering or peeling of the skin.

Other effects which may occur include:

Very rarely (less than 1 in 10,000 people are affected).

- Nausea and vomiting.
- Diarrhoea.
- Inflammation of the liver (hepatitis) may occur.

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

5 Storing this medicine

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 Sugar free 2% Oral Gel is: Miconazole 20 mg.

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

What the medicine looks like

Daktarin Sugar free 2% Oral Gel is a white gel with an orange flavour available in tubes of 15 g.

Product Licence holder:

McNeil Products Ltd, Maidenhead, Berkshire, SL6 3UG, UK.

Manufacturer:

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

This leaflet was revised August 2008.

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