

# Daktarin® Sugar Free 2% ORAL GEL

miconazole

- This medicine is used to treat superficial fungal infections of the mouth and throat.
- This medicine is for use by adults, children and infants 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 are allergic to the active substance, other similar antifungal medicines or any of the other ingredients of this medicine (listed in 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 treat superficial fungal infections of the mouth and throat. The gel contains miconazole which works by destroying the fungus.

This medicine is for use in adults, children and infants 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.

### ✗ Do not use this medicine...

- If you are allergic to the active substance, other similar antifungal medicines or any of the other ingredients of this medicine (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.
- If you are taking any of the following **medicines**:
  - *Warfarin* (a drug used to thin the blood)

- *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**)
- *Bepidil*, *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, pharmacist or dentist 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 *reboxetine*.

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. If you do breast-feed, do not apply the gel to your nipple to treat your baby.

### ⚠ Special warnings about this medicine

Daktarin Sugar Free 2% Oral Gel can cause severe allergic reactions. You must be aware of the signs of an allergic reaction while you are taking Daktarin Sugar Free 2% Oral Gel. See 'Possible side-effects'.

#### Infants and young children:

- Daktarin Sugar Free 2% Oral Gel is sticky. This ensures that it stays in the mouth as long as possible. It is important to 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 your baby.
- If the infant is 4-6 months old, and is premature or has slow development or problems swallowing, check with your doctor before using this medicine.

### ⚠ Some of the ingredients can cause problems

- This medicine contains less than 1 mmol sodium (23 mg) per 10 ml dose (maximum single dose for an adult), that is to say essentially 'sodium-free'.
- This medicine contains 7.85 mg of alcohol (ethanol) in each gram of gel which is equivalent to 0.00785 mg/mg (0.785 % w/w). The amount in single maximum dose of this medicine for an adult (2 measuring spoons or 10 ml of oral gel) is equivalent to less than 3 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- This medicine contains orange flavour (containing: citral, citronellol, linalool, geraniol, d-limonene) and cocoa flavour (containing: benzyl alcohol, benzyl benzoate) that may cause allergic reactions. Benzyl benzoate may cause mild local irritation.
- This medicine contains 0.000000285 mg of benzyl alcohol in each single maximum dose for an adult (10 ml of oral gel). Benzyl alcohol may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis"). Ask your doctor or pharmacist for advice if you have a kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis"). Benzyl alcohol may cause mild local irritation.

## 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. Do not swallow it straight away.
- If you are wearing dentures, remove them at bedtime and rub them with the gel. This will help

turn over ▶

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 into the child's mouth all 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 or problems swallowing, 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 <b>1,25 ml gel</b> (¼ measuring spoon) to the affected area <b>four times a day after meals.</b>

- 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 7 days after all the symptoms have cleared.
- If the infant is 4 - 6 months old, and is premature or has slow development or problems swallowing, 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 <b>2,5 ml gel</b> (½ measuring spoon) to the affected area <b>four times a day after meals.</b>

- Continue treatment for up to 7 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:**

- Severe allergic reactions including swelling of the face, lips, mouth, tongue or throat. Also hives, which is known as nettle rash or urticaria.
- Light headedness, generalised itch, wheezing or difficulty breathing or swallowing.
- Skin rashes which may be severe and include blistering or peeling of the skin, mouth, eyes and genitals.
- 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.

**Other effects which may occur include:**

**Common (less than 1 in 10 people)**

- Feeling sick (nausea)
- Mouth discomfort
- Being sick (vomiting)
- Regurgitation (bringing up swallowed food into the mouth)
- Dry mouth
- Abnormal product taste

**Uncommon (less than 1 in 100 people)**

- A change in the way some things taste.

**Other side-effects which may occur but it is unknown how often:**

- Inflammation of the liver (hepatitis)
- Diarrhoea
- Tongue discolouration
- Sore mouth
- Oversensitivity (allergic reactions)
- Acute generalised exanthematous pustulosis (AGEP): A serious illness with rapid blistering of the skin.
- Drug reaction with eosinophilia and systemic symptoms (DRESS): A group of symptoms including rash, fever and internal effects, with abnormal blood test results.

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

### 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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

## 5 Storing this medicine

Store below 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 Further information

**What's in this medicine?**

**The active ingredient in 1g of Daktarin Sugar Free 2% Oral Gel is:** Miconazole 20 mg.

**Other ingredients are:** Purified water, pregelatinised potato starch, ethanol, polysorbate 20, sodium saccharin, orange flavour (containing allergens: citral, citronellol, linalool, geraniol, d-limonene), cocoa flavour (containing allergens: benzyl alcohol, benzyl benzoate) 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 Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

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

**This leaflet was revised August 2022.**

Daktarin is a registered trade mark.

