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## 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 use 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**)
- *Bepiridil*, *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 breastfeeding

- Ask your doctor or pharmacist for advice before using this medicine if you are pregnant, think you are pregnant, planning to become pregnant or breastfeeding. If you do breastfeed, 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 23 mg of alcohol (ethanol) in 2.5 ml (1/2 measuring spoon) corresponding to 7.5 mg/g. The amount of 2.5 ml (1/2 measuring spoon) is equivalent to less than 1 ml of beer or 1 ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects. It may cause burning sensation on damaged skin.
- This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.
- This medicine contains polysorbate which can cause allergic reactions.
- This medicine contains benzyl benzoate which may cause allergic reactions.
- This medicine contains 2.3 picograms of benzyl alcohol per gram. Benzyl alcohol may cause allergic reactions and mild local irritation. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gaspings syndrome") in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist. Ask your doctor or pharmacist for advice if you are pregnant or breastfeeding. 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 liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

### 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.

turn over ▶

- If you are wearing dentures, remove them at bedtime and rub 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 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.
- An allergic skin reaction, that may include round or oval patches of redness and swelling of the skin, blistering, and itching (Fixed drug eruption). Darkening of the skin in affected areas, which might persist after healing, may also occur. Fixed drug eruption usually reoccurs at the same site(s) if the medication is taken again (Frequency unknown).

#### **Other effects which may occur include:**

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

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

After first opening, discard once the treatment for one episode of fungal infection is completed.

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 Daktarin Sugar Free 2% Oral Gel is miconazole. Each gram of gel contains 20 mg of miconazole.

**Other ingredients** are glycerol, ethanol, carbomers, polysorbate 20 (E432), saccharin sodium (E954), sodium hydroxide, cocoa flavour (contains ethanol, benzyl alcohol and benzyl benzoate), orange flavour and water.

##### **What the medicine looks like**

Daktarin Sugar Free 2% Oral Gel is a white, sugar-free gel with an orange flavour available in aluminium tubes of 15 g. A 5 ml plastic spoon, marked with ¼ and ½ graduations (1.25 & 2.5 ml) is provided in the pack.

**Product Licence holder:** McNeil Products Limited, 50-100 Holmers Farm Way, High Wycombe, Buckinghamshire, HP12 4EG, UK.

**Manufacturer:** JNTL Consumer Health (France) SAS, Domaine de Maigremont, 27100 Val De Reuil, France.

**This leaflet was revised September 2025.**

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