

**PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS
(PREPARATIONS) - 1986**

The medicine is dispensed without a doctor's prescription

**Product name and its form
Daktarin® Oral Gel**

Active ingredient and its concentration:

Miconazole 20 mg/g

Inactive ingredients and allergens in the product - see section 6 "Further Information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

The medicine is not intended for infants below the age of 6 months or for infants whose swallowing reflex is not sufficiently developed, due to the risk of choking.

Use it properly. Consult a pharmacist if you need further information. Refer to the doctor if the signs of the disease (symptoms) worsen or do not improve.

1. WHAT IS THIS MEDICINE INTENDED FOR?

For the treatment and prevention of oral mycosis and fungal infections of the upper gastrointestinal tract (throat, esophagus, stomach, intestines).

Therapeutic group: Antifungal, of the imidazole derivatives.

2. BEFORE USING THE MEDICINE

Do not use this medicine if:

- you are sensitive (allergic) to miconazole, to similar antifungals or to any of the additional ingredients contained in the medicine. For the list of additional ingredients, see section 6 "Further Information".

- you are suffering from any liver disease.

- in infants below the age of 6 months or in infants whose swallowing reflex is not sufficiently developed, due to the risk of choking.

- you are taking any of the following medicines:

- terfenadine, astemizole and mizolastine (medicines for hay fever or allergy).

- cisapride (a medicine used to treat certain digestive problems).

- cholesterol-lowering medicines, such as simvastatin and lovastatin.

- midazolam (taken by mouth) and triazolam (medicines used to treat anxiety and sleep disorders).

- pimozide and sertindole (medicines used to treat psychotic disorders).

- quinidine and dofetilide (medicines used to treat heart rhythm problems).

- certain medicines used to treat migraine such as ergot alkaloids.

Do not use if any of the above applies to you. If you are uncertain, refer to a doctor or pharmacist before using this medicine.

Special warnings regarding use of the medicine

If the gel blocks the throat passageway, infants and children may choke.

Daktarin Oral Gel is a sticky substance, which enables it to stay in the mouth for as long as possible.

Important: Make sure that the gel does not close off the child's throat, as this could cause the child to choke. For this purpose, take the following precautions:

- Place the gel in the front of the mouth and never put it in the back of the throat.
- Divide the required dose into small portions. Never put the entire dose in the child's mouth at once.
- Apply the gel to the affected areas of the mouth (white patches) with a clean finger and according to the doctor's instructions.

- If you are breastfeeding, never apply the gel to your nipple in order to treat your baby.

Blood tests

If you are taking blood thinners (anticoagulants) or phenytoin (a medicine for epilepsy), the doctor may want to check the levels of the medicines in your blood via a blood test.

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. It is especially important to inform the doctor or pharmacist if you are taking:

Do not use Daktarin Oral Gel together with the following medicines:

- medicines for hay fever or allergy - terfenadine, astemizole and mizolastine.
- cisapride, a medicine used to treat certain digestive problems.
- cholesterol-lowering medicines, such as simvastatin and lovastatin.
- midazolam (taken by mouth) and triazolam, medicines used to treat anxiety and sleep disorders.
- pimozide and sertindole, medicines used to treat psychotic disorders.
- medicines used to treat heart rhythm problems - quinidine and dofetilide.
- certain medicines used to treat migraine, such as ergot alkaloids.

Do not start treatment with Daktarin Oral Gel and inform your doctor if you are taking any of the medicines listed above.

Combination with some medicines may require monitoring or a dosage change of either Daktarin Oral Gel or of the other medicine. Tell your doctor before taking, or if you are already taking, one of the following medicines:

- anticoagulants such as warfarin.
- medicines for the treatment of the AIDS virus, such as HIV protease inhibitors, e.g., saquinavir.
- certain medicines for the treatment of cancer, such as busulfan, docetaxel and a group of medicines known as 'vinca alkaloids'.
- medicines that act on the heart and blood vessels called calcium channel blockers, such as dihydropyridines and verapamil.
- cyclosporine, tacrolimus and sirolimus, which are usually given after an organ transplant.
- phenytoin and carbamazepine, for treatment of epilepsy.
- alfentanil for pain.
- certain tranquilizers for the treatment of anxiety or sleeping difficulties, such as buspirone, alprazolam, brotizolam or intravenous midazolam.
- rifabutin for tuberculosis.
- methylprednisolone, a medicine given by mouth or injection for the treatment of inflammations.
- ebastine, a medicine used to treat allergy.
- reboxetine, a medicine used to treat depression.
- oral medicines used to treat diabetes, such as sulphonylureas, such as chlorpropamide and glibenclamide.
- sildenafil, a medicine used to treat male impotence.
- trimetrexate, a medicine used to treat a certain type of pneumonia.
- cilostazol or disopyramide, medicines that act on the heart and blood vessels.

Tell your doctor before taking, or if you are already taking, any of the medicines listed above. This can alter the treatment.

Do not start treatment with a new medicine without first consulting the doctor or pharmacist.

Pregnancy and breastfeeding

If you are pregnant or if you think you might be pregnant, inform the doctor who will decide if you can use the medicine.

If you are breastfeeding, inform the doctor who will decide if you can use the medicine. If you are breastfeeding, never apply the gel to your nipple in order to treat your baby.

Driving and use of machines

It is unlikely that Daktarin Oral Gel will affect the ability to drive or to operate machinery.

Important information regarding some of the ingredients of the medicine

• Daktarin Oral Gel contains 0.00785 g of alcohol (ethanol) in each 1 g which is equivalent to 0.00785 mg/mg (0.785%w/w). The amount in 1 g 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.

• Orange flavour and cocoa flavour

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.

This medicinal product contains 0.000000017 mg of benzyl benzoate in each single maximum dose for an adult (10 ml of oral gel). Benzyl benzoate may cause mild local irritation.

• Benzyl alcohol

This medicine contains 0.0000000285 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.

• Daktarin Oral Gel contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. HOW SHOULD THE MEDICINE BE USED?

Check with the doctor or pharmacist if you are uncertain.

- To open the tube, unscrew the cap and pierce the sealed part of the tube, using the pin on the top of the cap.
- For oral use only.
- Do not swallow the gel straight away, rather, keep it in your mouth for as long as possible, thereby enabling the medicine to remain in contact with the mouth for a while, then swallow.
- If the infection is only in the mouth, apply the gel to the affected area with a clean finger.
- If you have dentures, take them out at night, and brush them with Daktarin Oral Gel. This will prevent them from also becoming infected.
- **Do not exceed the recommended dose.**
- Take the medicine after a meal.
- If you are giving the gel to a child or an infant over 6 months of age, be sure there is no risk of choking, **by dividing the required dose into small portions – never place the entire dose in the child's mouth at once. Place the gel at the front of the mouth. Never place the gel in the back part of the throat.**

The dosage of the medicine depends on the type of fungus and its location.

Recommended dosage for treatment of oral mycosis and fungal infection of the throat:

Children above 2 years of age and adults:

½ measuring spoon (2.5 ml) of gel, 4 times a day, after meals.

Children from 6 months to 2 years of age:

¼ measuring spoon (1.25 ml) of gel, 4 times a day, after meals. Divide the required dose into small portions and apply to the affected area with a clean finger.

The dosage for the treatment of fungal infection of the stomach and intestines will be determined by the doctor only.

Continue the treatment for at least one week after all the clinical symptoms have gone away. This will prevent the symptoms from coming back.

If the symptoms persist, refer to the doctor.

Do not exceed the recommended dose.

This medicine is not intended for infants below the age of 6 months or for infants whose swallowing reflex is not sufficiently developed, due to the risk of choking.

Take care to measure the dose using a measuring spoon, or special measuring cup, dropper, etc. Avoid contact with the eyes.

Taking an overdose can cause vomiting and diarrhea.

If you or your child accidentally take a higher dosage, refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult a doctor.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding the use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Daktarin Oral Gel may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop using Daktarin Oral Gel and refer to a doctor straight away if you notice any of the following. You may need medical treatment:

- Sudden swelling of the face, lips, tongue or throat; difficulty swallowing; urticaria and breathing problems (angioedema, anaphylactic reaction); severe irritation, reddening or blistering of the skin. These may be signs of a severe allergic reaction.
- Severe skin problems, including peeling and/or rash with small pus-containing pimples (with a fever) or blistering of the skin, mouth, eyes and genitals (toxic epidermal necrolysis or Stevens-Johnson Syndrome).
- Dizziness, widespread rash, wheezing or difficulty breathing.
- If you are taking medicines to thin the blood (anticoagulants), such as warfarin: unexpected bleeding or bruising, nosebleeds, coughing up blood, blood in the urine, black tarry stools or coffee ground vomit.

Refer to a doctor if you notice the following side effect, whose frequency is unknown:

Rash with festering sores (acute generalised exanthematous pustulosis)

Common side effects:

Dryness in the mouth, nausea, vomiting, mouth discomfort, gastroesophageal reflux, strange taste of the product in the mouth

Uncommon side effects:

Loss of or abnormal sense of taste

Side effects that occur rarely:

Choking

Diarrhea

Inflammation of the liver (hepatitis)

Sore mouth

Tongue discoloration

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

If you experience any of these side effects, or if you suffer from a side effect not mentioned in the leaflet, refer to the doctor or pharmacist immediately.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants to avoid poisoning.

Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.

Store the gel in its original package.

Store below 30°C.

Do not use the product beyond 3 months after first opening.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Glycerol, purified water, pregelatinized potato starch, ethanol 96%, polysorbate 20, sodium saccharin, cocoa flavor, orange flavor.

The product contains:

Sodium saccharin 1.00 mg/g

What does the medicine look like and what are the contents of the package -

Daktarin Oral Gel is provided in a tube containing 40 g of a white, uniform, sugar-free, orange flavored gel. A 5 ml plastic spoon, marked with a 2.5 ml line, is supplied with the package.

Registration Holder and address: J-C Health Care Ltd., Kibbutz Shefayim 6099000, Israel

Manufacturer and address: Janssen Pharmaceutica N.V., Beerse, Belgium

Revised in June 2023 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
038-08-20857