

DAKTARIN

Oral Gel

Before you start to take your medicine, please read this leaflet carefully all the way through as it contains important information. If there is anything that you do not understand or if you need further information or advice, you should ask your doctor or pharmacist who will be pleased to help you. Please do not throw this leaflet away until you have finished taking the full course of your medicine. You may need to refer to it again.



WHAT IS DAKTARIN FOR?

DAKTARIN Oral Gel is used to treat fungal infections of the mouth or throat in adults and children 4 months and older. For a child between 4 and 6 months of age, be sure they do not have any swallowing problems before treating them with the oral gel (see *WHEN NOT TO TAKE DAKTARIN*).



WHEN NOT TO TAKE DAKTARIN

Due to risk of choking, do not use DAKTARIN in infants less than 4 months of age or in infants less than 5-6 months of age if the infant is pre-term or has problems swallowing.

Do not take DAKTARIN:

- if you have any kind of liver disease;
- if you are allergic to miconazole or to any of the other ingredients it contains;
- if you are taking certain medicine(s)

The effects and/or side effects of many medicines can be increased or decreased when taken with DAKTARIN.

Examples of medicines that must never be taken while you are taking DAKTARIN Oral Gel:

- certain medicines for allergy, namely terfenadine, astemizole and mizolastine;
- cisapride, a medicine used for certain digestive problems;
- certain medicines that lower your cholesterol, for example simvastatin and lovastatin;
- midazolam (by mouth) and triazolam, medicines that are taken for anxiety or to help you sleep (tranquilizers);
- pimozide and sertindole, medicines for certain psychiatric disorders;
- halofantrine, an antimalaria medicine;
- certain medicines used in the treatment of migraine, such as ergot alkaloids (Cafergot®);
- certain medicines used to treat irregular heartbeat, namely bepridil, quinidine, and dofetilide.
- warfarin

If you take, or plan to take, any other medicine, ask a doctor or pharmacist before you start DAKTARIN.

WHAT SPECIAL PRECAUTIONS SHOULD YOU TAKE?

DAKTARIN can cause severe allergic reactions. You must be aware of the signs of an allergic reaction while you are taking DAKTARIN. See 'UNDESIRE EFFECTS'.



Infants and young children

DAKTARIN 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 throat as the child could choke on it. Take the following precautions:

- divide each application in smaller portions - never put the whole amount into the child's mouth all at once;
- apply the gel to the affected areas of the mouth (white patches) with a clean finger and according to advice from your doctor or pharmacist,
- never put a large portion of gel in the back of the throat.
- if you are breast-feeding, never apply the gel to your nipple to treat the baby.



Pregnancy

If you are pregnant or think you may be, you should inform your doctor, who will decide if you can take DAKTARIN.



Breast-feeding

If you are breast-feeding, you should consult your doctor first, who will decide if you can take DAKTARIN. If you do breast-feed, do not apply the gel to your nipple to treat your baby.



Other medicines

Tell your doctor, dentist, and pharmacist what medicines you are taking. Some medicines must not be taken at the same time as DAKTARIN, and if certain medicines are taken at the same time, changes may have to be made (to the dose, for example). (see *WHEN NOT TO TAKE DAKTARIN*)

Combination with some other medicines may require additional monitoring for the drug effects or side effects, or a dose change for either DAKTARIN or the other medicine.

Examples are:

- the blood thinning medicine warfarin
- certain medicines that are taken by mouth for the treatment of diabetes
- certain AIDS medicines such as HIV protease inhibitors;
- certain medicines used in the treatment of cancer;
- some products that act on the heart and blood vessels (certain calcium-channel blockers);
- cyclosporine A, tacrolimus and sirolimus, which are usually given after an organ transplant;
- phenytoin, a medicines used for the treatment of epilepsy;
- certain anesthetics used in hospitals such as alfentanil;
- sildenafil, a medicines to treat male impotence;
- certain medicines for anxiety or to help you sleep (tranquillizer);
- certain medicines for tuberculosis;
- methylprednisolone, a medicines given by mouth and injection for inflammation;
- trimetrexate, a medicines used to treat a certain type of pneumonia.
- ebastine, a medicines used for allergy;
- reboxetine, a medicines used to treat depression.

If you are using any of these or any other medicines , please discuss the matter with your doctor or pharmacist.

While taking DAKTARIN Oral Gel do not start a new medicine without first informing your doctor or pharmacist.



Driving or operating machinery

DAKTARIN does not affect your alertness or driving ability.



HOW TO TAKE DAKTARIN AND HOW MUCH

DAKTARIN comes in the form of oral gel to be taken by the mouth. The amount of DAKTARIN you will need to take and how long will depend on the type of fungus and the location of the infection. Your doctor will tell you exactly what to do. Continue the treatment for at least a week after all symptoms have disappeared.

The gel should not be swallowed immediately, but kept in the mouth as long as possible. If you are wearing dentures, remove them at bedtime and brush them with the gel. This can prevent your dentures from becoming infected too.

Recommended dosage for treatment of infections of the mouth or throat:

Adults and children 2 years and older

2.5 mL (1/2 measuring spoonful) of gel, applied four times a day after meals;

Children 4 months to 2 years

1.25 mL (1/4 measuring spoonful) of gel, applied four times a day after meals. Divide each dose into smaller portions and apply to the affected areas with a clean finger.

WHAT TO DO IF YOU FORGET TO USE YOUR MEDICINE

If you forget to use your gel, do not take the missed dose, but take the next dose as usual and continue your course of medicine

To open the tube unscrew the cap and pierce the seal of the tube using the pin on the top of the cap.



UNDESIRE D EFFECTS

If DAKTARIN blocks the throat, infants and children may choke.

Severe allergic reactions have been reported with DAKTARIN. The signs of a severe allergic reaction may include:

- A swollen face, lips, mouth, tongue or throat
- Difficulty swallowing or breathing
- Itchy rash (hives)
- Fainting

Stop taking DAKTARIN and get emergency medical help straight away if you notice or suspect any of these side effects.

Common (affects less than 1 in 10 people):

- Change in sense of taste
- Dry mouth, mouth discomfort
- Nausea, vomiting
- Strange taste to the medicine

Very rare (affects less than 1 in 10000 people):

- Life-threatening rash with blisters and peeling skin over much of the body (toxic epidermal necrolysis)
- Severe rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome)
- Hives
- Skin rash
- Red rash covered with small pus-filled bumps that can spread over the body, sometimes with a fever (acute generalized exanthematous pustulosis)
- Severe rash over the body, usually with fever and swollen lymph nodes, and effects on blood cells and organs (drug reaction with eosinophilia and systemic symptoms or DRESS)
- Choking
- Diarrhea
- Sores in the mouth
- Tongue discoloration
- Inflamed liver

Nausea and vomiting are very common side effects (may affect more than 1 in 10 people) in children and bringing up stomach contents into the mouth (regurgitation) is common.

If any of the side effects get serious, or you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately.

**OVERDOSE**

If you have taken too much DAKTARIN, inform your doctor. Possible signs of overdose include vomiting and diarrhea.

Information for the doctor in case of overdose

- *Treatment is symptomatic and supportive.*
- *There is no specific antidote.*

**HOW TO STORE DAKTARIN**

Keep DAKTARIN between 15 and 30°C (normal room temperature). This medicine can be kept for only a limited period. Do not use DAKTARIN after the date (month and year) printed after “EXP”, even if it has been stored properly.

You are advised to return unused medicines to your pharmacist.

**WHAT IS IN DAKTARIN?**

DAKTARIN is a medicine against infection with fungi including yeasts.

The active ingredient in DAKTARIN is miconazole.

DAKTARIN comes in the form of oral gel.

- tube of 15 grams;
- 1 gram of gel contains 20 milligrams of miconazole;
- the gel also contains: glycerin, water, starch, ethanol 96%, tweens, saccharin sodium, cocoa flavour and tetraorange.

Batch Releaser:

Janssen Pharmaceutica NV
Turnhoutseweg 30
B-2340 Beerse, Belgium

Product Registrant:

Johnson & Johnson Pte Ltd
2 Science Park Drive
#07-13, Ascent
Singapore Science Park 1
Singapore 118222

Latest update of this package insert:

31 August 2017(CCPI 23 November 2016)

What you should know about medicines...

Always inform your doctor or pharmacist if you are using other medicines because some drugs should not be taken together.

It is important that you use medicines correctly, that is, you should:

- always carefully read the full patient information leaflet;
- use medicines only for the purpose for which you were given the medicines;
- use medicines only in the prescribed amount;
- use medicines only for the prescribed period of time.

Keep all medicines out of the reach of children.

Never allow others to use medicines recommended for you and never use medicines prescribed for others.

Keep all medicines in their original packaging and in a dry place (never in the bathroom, for example!).

Make a habit of returning unused or old medicines to your pharmacist.

If someone has taken an overdose of a medicine, call a doctor or the poison control centre.