

PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully because it contains important information for you

DAKTARIN oral gel is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless you still need to use DAKTARIN® oral gel carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after *one week*.

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DAKTARIN® oral gel

Miconazole 20 mg/g

Ethyl alcohol content: 0,73 % m/m

1. WHAT DAKTARIN ORAL GEL CONTAINS

- The active substance is miconazole.
- The other ingredients are potato starch, sodium saccharin, polysorbate, orange cacao flavour, alcohol, glycerol and water.

2. WHAT DAKTARIN ORAL GEL IS USED FOR

DAKTARIN is a medicine used for treating and preventing infection by fungi including yeasts (e.g. Candida).

DAKTARIN oral gel is used for fungus infections of the mouth.

3. BEFORE YOU USE DAKTARIN ORAL GEL

Do not use DAKTARIN ORAL GEL:

- *Do not use DAKTARIN oral gel in infants less than 6 months of age because of risk of choking*
- if you or your child are hypersensitive (allergic) to *miconazole* or any of the other ingredients of DAKTARIN oral gel. (see *WHAT DAKTARIN ORAL GEL CONTAINS*)
- if you or your child have any kind of liver disease
- if you are taking any other medication(s) unless you have advice from your healthcare provider. (see below: Taking other medicines with DAKTARIN oral gel)

Take special care with DAKTARIN oral gel

- Avoid contact with eyes
- Infants and small children:

DAKTARIN oral gel is sticky. This ensures that it stays in the mouth as long as possible.

Important: make sure that the gel does not close off the child's throat as the child could choke on it; you should therefore take the following precautions:

- divide each application in smaller portions (never put the whole amount in the mouth of the child at once;
- apply the gel to the affected areas of the mouth (white patches) and ulcers (sores) according to the advice from your doctor or pharmacist;
- never put a large portion of gel in the back of the throat.

If you take any of the following medications:

1. blood thinning medication, e.g. warfarin;
2. certain medicines that are taken by mouth for the treatment of diabetes;
3. phenytoin, a medicine used for the treatment of epilepsy; additional monitoring or a dose change of either DAKTARIN oral gel or the other medicine may be required

Using DAKTARIN oral gel with food and drink

The gel must be used after meals.

Pregnancy and Breastfeeding

DAKTARIN oral gel should not be used during pregnancy as safety has not been demonstrated.

DAKTARIN oral gel should not be used if you are breastfeeding.

If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Taking other medicines with DAKTARIN oral gel

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of DAKTARIN oral gel with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

Examples of medicines that must never be taken while you are on DAKTARIN oral gel:

- certain medicines for allergies, namely astemizole and mizolastine;
- cisapride, a medicine used for certain digestive problems;
- certain medicines that lower your cholesterol, e.g. simvastatin and lovastatin;
- midazolam (by mouth) and triazolam, medicines that are taken for anxiety or to help you sleep (tranquillisers);
- pimozide and sertindole, medicines for certain psychiatric disorders;
- halofantrine, an antimalaria medicine;
- certain medicines used in the treatment of migraine, e.g. ergot alkaloids (Cafergot);
- certain medicines used to treat irregular heart beat rhythms, e.g. bepridil, quinidine, and dofetilide.

Combination with some other medicines may require additional monitoring or a dose change for either DAKTARIN oral gel or the other medicine. Examples are:

- blood thinning medication, e.g. 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 or blood vessels (certain calcium-channel blockers);
- ciclosporine A, tacrolimus and sirolimus, which are usually given after an organ transplant;
- phenytoin, a medicine used for the treatment of epilepsy;
- certain anaesthetics used in hospitals such as alfentanil;
- sildenafil, a medicine to treat male impotence;
- certain medicines for anxiety or to help you sleep (tranquillizer);
- certain medicines for tuberculosis;
- methylprednisolone, a medicine given by mouth and injection for inflammation;
- ebastine, a medicine used for allergy;
- reboxetine, a medicine used to treat depression.

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

4. HOW TO USE DAKTARIN ORAL GEL

Always take DAKTARIN oral gel exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

The gel should not be swallowed immediately, but kept in the mouth as long as possible.

Spread evenly over the affected areas taking care to properly cover oral ulcerations and other lesions.

Apply three to four times daily depending on the severity of the infection.

Apply the gel regularly until all signs of the infection have disappeared.

Thus, the medicine can remain in contact with the mouth for a longer period.

If you are wearing dentures, you should preferably remove them at bedtime and brush them with the gel. In this way, you can prevent your dentures from becoming infected too.

Continue using for another two days after the infection has cleared.

If you use more DAKTARIN oral gel than you should:

If you have taken too much DAKTARIN oral gel, you might suffer from vomiting and diarrhoea.

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

5. POSSIBLE SIDE EFFECTS

DAKTARIN oral gel may cause side effects.

Tell your doctor if you notice any of the following:

- nausea (feeling sick),
- vomiting,
- regurgitation,
- loss of or abnormal taste,
- dry mouth,

- mouth discomfort
- diarrhoea,
- inflammation of the mouth,
- tongue discolouration

as the above may occur frequently.

If any of the following happen, stop taking DAKTARIN oral gel and tell your doctor immediately or go to the casualty department at your nearest hospital:

- a widespread rash with peeling skin and blisters in the mouth, eyes and genitals (Toxic Epidermal Necrolysis or Stevens-Johnson syndrome).
- skin rash, itching, hives, shortness of breath, and / or swollen face (hypersensitivity reaction).

These are all very serious side effects. If you have them, you may have a serious allergic reaction to DAKTARIN oral gel. You may need urgent medical attention or hospitalisation. All of these very serious side effects are very rare.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- lack of appetite, nausea, vomiting, tiredness, abdominal pain, jaundice, very dark urine and pale stools as these may be signs of inflammation of the liver.

These are all serious side effects. You may need urgent medical attention. Serious side effects are rare.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking DAKTARIN oral gel, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF DAKTARIN ORAL GEL

Keep well closed.

Store at or below 25 °C.

Do not freeze.

This medicine can be kept for only a limited period. Do not use DAKTARIN oral gel after the date (month and year) printed after "EXP", even if it has been stored properly.

You are advised to return old medicine to your pharmacist.

KEEP ALL MEDICINES OUT OF THE REACH AND SIGHT OF CHILDREN.

7. PRESENTATION OF DAKTARIN ORAL GEL

DAKTARIN oral gel is supplied in aluminium tubes with white polyethylene caps containing 30g or 40g of gel.

8. IDENTIFICATION OF DAKTARIN ORAL GEL

White, homogenous gel with an orange flavour.

9. REGISTRATION NUMBER/ REFERENCE NUMBER

L/20.2.2/183

10. NAME AND ADDRESS OF REGISTRATION HOLDER



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