PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

Schedule 2

DAKTARIN® oral gel

Miconazole 20 mg/g

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.
- Do not share DAKTARIN oral gel with any other person
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days

What is in this leaflet

1. What DAKTARIN oral gel is and what it is used for
2. What you need to know before you take DAKTARIN oral gel
3. How to take DAKTARIN oral gel
4. Possible side effects
5. How to store DAKTARIN oral gel
6. Contents of the pack and other information

1. What DAKTARIN ORAL GEL is and what it is used for

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

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

2. What you need to know before you use DAKTARIN ORAL GEL

Do not use DAKTARIN ORAL GEL:

- *Due to risk of choking, do not use DAKTARIN oral gel in infants less than 4 months of age or in infants less than - 6 months of age if the infant is pre – term or has problems swallowing.*
- if you or your child are allergic to *miconazole,* similar antifungal medicines 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) with a clean finger and according to the advice from your doctor or pharmacist;
  - never put a large portion of gel in the back of the throat.
  - If you are breastfeeding, your infant never apply the gel to your nipple to treat the baby.
  - DAKTARIN ORAL GEL can cause severe allergic reactions. You must be aware of the signs of an allergic reaction while you are taking DAKTARIN ORAL GEL. (See POSSIBLE SIDE EFFECTS)

  If you take any of the following medications:
  1. the blood thinning medicine, 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.

Other medicines and DAKTARIN oral gel

Always tell your healthcare professional if you are taking any other medicine. This includes complementary or traditional medicines.

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;
- certain medicines used to treat irregular heart beat rhythms, e.g. bepridil, quinidine, and dofetilide.
- The blood thinning medicine, warfarin

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

- certain medicines that are taken by mouth for the treatment of diabetes;
- certain AIDS medicines such as HIV protease inhibitors such as ritonavir and saquinavir;
- certain medicines used in the treatment of cancer;
- some medicines that act on the heart or blood vessels (certain calcium-channel blockers);
- ciclosporin, 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 (tranquilliser);
- 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 using DAKTARIN oral gel do not start a new medicine without first informing your doctor or pharmacist

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 your infant.

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

Driving and using machines

DAKTARIN oral gel does not affect alartness or driving ability.

3. How to use DAKTARIN ORAL GEL

Do not share medicines prescribed for you with any other person.

Recommended dosages:

Adults and children 2 years and older: ½ measuring spoonful (2.5 ml) of gel;

Children 4 months to 2 years: ¼ measuring spoonful (1.25 ml)

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

Using a clean finger, spread the gel 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.

If you are wearing dentures, you should 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 overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control center.

4. Possible side effects

DAKTARIN oral gel may cause side effects.

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

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

Stop using DAKTARIN ORAL GEL and get emergency medical help straight away if you notice or suspect any of these side effects

Tell your doctor if you notice any of the following:

- nausea (feeling sick),
- vomiting,
- regurgitation, (bringing up stomach contents into the mouth)
- loss of or abnormal taste,
- dry mouth,
- mouth discomfort
- diarrhoea,
- inflammation of the mouth,
- sores in 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:

- choking
- liver problems

- 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)
- skin rash, itching, hives
- Red rash covered with small pus-filled bumps that can spread over the body, sometimes with a fever (acute generalised 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)

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 DAKTARIN ORAL GEL are included in this leaflet. Should your general health worsen or if experience any untoward effects while taking DAKTARIN oral gel, please consult your doctor, pharmacist or other health care professional for advice.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via “6.04 Adverse Drug Reaction Reporting Form” found online under SAHPRA’s publications: https://www.sahpra.org.za/Publications/index/8.
By reporting side effects, you can help provide more information on the safety of GYNO-DAKTARIN VC.

Alternatively, suspected adverse reactions may be reported directly to Janssen Pharmaceutica (see section 7 for contact details or visit www.janssen.com).

5 How to store DAKTARIN ORAL GEL

Keep well closed.

Store below 30 °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.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

6 Contents of the pack and other information

What DAKTARIN ORAL GEL contains:

The active substance is miconazole. 1 g of gel contains 20 mg of miconazole.

Other excipients are:

gelatinized potato starch, sodium saccharin (E 954), polysorbate 20, orange -flavour, cocoa flavour, ethanol 96%, glycerol, purified water.

What DAKTARIN ORAL GEL looks like and contents of the pack

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

Holder of certificate of registration

JANSSEN PHARMACEUTICA (Pty.) Ltd.

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Access to the corresponding Professional Information

Included in the carton, accompanying this patient information leaflet.

- 18 October 1979 (Date of registration)