

Miragel™ 2% Oral gel

miconazole (base)

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What Miragel™ is and what they are used for

Miragel™ Oral gel is used to treat infections of the mouth and throat (e.g. thrush). Miragel™ Oral gel is an antifungal. These medicines work by treating infections caused by fungi, including yeast. Your doctor may have prescribed Miragel™ Oral gel for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. Before you use Miragel™

When you must not use it:

- Do not use Miragel™ Oral gel if you know you are allergic to any of the ingredients. (See section. 6 of this leaflet for a list of ingredients).
- Signs of allergy include a skin rash, itching, shortness of breath and/or a swollen face, lips, tongue or other parts of the body.
- Do not use Miragel™ Oral gel if you have liver disease. Miragel™ Oral gel could make the symptoms of your liver disease worse.
- Do not give Miragel™ Oral gel to an infant below the age of 6 months. The safety of this medicine in infants under 6 months of age has not been established.
- Do not use Miragel™ Oral gel if the packaging is torn or shows signs of tampering. Do not use Miragel™ Oral gel beyond the expiry date on the pack.
- Do not use Miragel™ Oral gel if you are taking any of the following medicines because it may affect the way these medicines work:
- cisapride (used for digestive problems).
 - simvastatin or lovastatin (used to lower cholesterol).
 - certain medicines used to relieve anxiety or to help you sleep (oral midazolam or triazolam).
 - pimozide (used to treat mental disorders).
 - quinidine (used to treat irregular heart beats).

Before you start to use it:

Certain people must use Miragel™ Oral gel with caution. Ask your doctor for advice.

Tell your doctor or pharmacist if:

- you are pregnant or planning to become pregnant.
 - you are breast feeding or wish to breastfeed.
- Your doctor or pharmacist will advise whether you should use Miragel™ Oral gel or if you need to adjust the dose or adapt your treatment.

Other medicines:

Tell your doctor or pharmacist if you are taking any other medicines including medicines you can buy from a pharmacy, supermarket or health food shop.

In particular, tell your doctor or pharmacist if you are taking any of the following:

- cisapride (used for digestive problems).
- terfenadine and astemizole (antihistamines).
- simvastatin or lovastatin (used to lower cholesterol).
- certain medicines to relieve anxiety or to help you sleep (midazolam by mouth or triazolam).
- pimozide (used to treat mental disorders).
- quinidine (used to treat irregular heartbeats).

If you have not told your doctor or pharmacist about any of the above, tell them before you start using or are given Miragel™ Oral gel.

There may be some other medicines that may cause problems if used together with Miragel™ Oral gel. So, make a point of telling your doctor or pharmacist which medicines you are taking at the moment, and before you start taking any new medicines. They will tell you which medicines should not be taken or what other measures (for example, a change of dose) are necessary.

- Some medicines, which may be affected by Miragel™ Oral gel or may affect how well Miragel™ Oral gel works, are:
- medicines which slow blood clotting (warfarin or other anticoagulants) because bleeding or bruising may occur.
 - certain medicines used to treat AIDS, such as saquinavir.
 - certain medicines used to treat cancer, such as docetaxel.
 - certain calcium channel blockers (used to treat high blood pressure or heart problems) such as verapamil and bepridil.
 - cyclosporin, sirolimus or tacrolimus which are drugs usually given after an organ transplant to prevent organ transplant rejection.
 - medicines taken by mouth for diabetes such as tolbutamide, tolazamide, glipizide and glimepiride.
 - medicines for epilepsy (phenytoin or carbamazepine).
 - alfentanil (used in surgery for pain relief and to help anaesthesia).
 - sildenafil (used to treat male impotence).
 - certain medicines for anxiety or to help you sleep (tranquillisers) such as triazolam.
 - certain medicines used to treat tuberculosis.
 - methylprednisolone (given by injection to reduce inflammation).
 - disopyramide (used to treat unusual heart beat)

3. How to use Miragel™

How much to use:

Adults and children (2 years of age and older):

Half (½) tea spoon four times a day after food.

Infants (6-24 months): One quarter (¼) of tea spoon four times a day after food.

How to use it:

Opening Instructions:

1. Unscrew the cap.
2. Reverse the cap and push it firmly into the neck of the tube to fully puncture the safety seal.

Follow these steps to ensure you use Miragel™ Oral gel properly:

After you have finished eating, drop the measured amount of gel onto the tongue and keep it in the mouth for as long as possible before swallowing.

The gel is sticky to make sure it stays in the mouth as long as possible.

If you are giving the gel to infants and young children the measured dose should be given in small amounts placed in the front of the mouth. Do not give the whole amount at once. Do not put the gel in the back of the mouth. This is to make sure that the throat does not become blocked by the gel.

If you wear dentures, apply a thin layer of Miragel™ Oral gel directly on to the dentures in the evening and leave it on overnight. Make sure you wash your dentures before putting them back in, in the morning.

Continue treatment for at least a week after symptoms have disappeared. This is to ensure that the treatment is complete.

If you forget to use it:

If you forget to use Miragel™ Oral gel, do so as soon as you remember, and then go back to using it as you would normally. If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to. Do not use a double dose to make up for the one you missed.

If you have used too much (overdose)

Immediately telephone your doctor, or go to the Emergency Department at your nearest hospital immediately if you think you or anybody else has used too much Miragel™. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Information for the doctor in case of overdose

Miragel™ Oral gel has limited absorption and therefore systemic effects are not expected. There is no specific antidote.

While you are using Miragel™ Oral gel:

Things you must do:

- Avoid contact with eyes.

Things you must not do

- Do not use a medicine for any purpose other than for the purpose it has been recommended for you.
- Do not use more than the recommended amount.
- Do not give this medicine to anyone else even if their symptoms seem similar to yours.

4. Possible side effects

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Miragel™ Oral gel may have some unwanted side effects in a few people, even though it is usually well tolerated at the recommended dose.

Tell your doctor if any of the following symptoms happen and they worry you: nausea, vomiting, diarrhoea, loss of appetite, generally feeling unwell and chills.

Tell your doctor immediately if you notice any of the following: yellowing of the skin and eyes, fever, dark coloured urine, severe blisters and bleeding in the lips, eyes, mouth, nose and genitals.

Tell your doctor immediately and do not take your next dose of Miragel™ Oral gel if you experience: signs of allergy such as skin rash, reddening, blisters or itching, swelling of the face, lips or other parts of the body, shortness of breath or wheezing.

Other side effects not listed above may also occur in some people. Do not hesitate to report any other side effects to your doctor or pharmacist.

5. How to store Miragel™

- Keep out of the reach and sight of children.
- Do not store above 30 °C.
- Do not use Miragel™ Oral gel after the expiry date which is stamped on the pack and tube.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Miragel™ Oral gel contain

- The active substance is miconazole (base).
- The other ingredients are glycerol, liquid orange flavor, polysorbate 80, potato starch pregelatinized, saccharin sodium and purified Water.

What Miragel™ Oral gel look like and contents of the pack

Miragel™ Oral gel is a white to off-white, slightly opaque, smooth gel. Miragel™ Oral gel comes in 40 g Aluminum collapsible tubes.

Marketing Authorisation Holder and Manufacturer

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To report any side effect(s):

- Saudi Arabia:
National Pharmacovigilance Center (NPC)
Fax: +966-11-205-7662
E-mail: npc.drug@sfd.gov.sa, Website: www.sfd.gov.sa/npc
- Other GCC States:
– Please contact the relevant competent authority.

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THIS IS A MEDICAMENT

- Medicament is a product that affects your health, and its consumption contrary to instructions is dangerous for you.
 - Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
 - The doctor and the pharmacist are experts in medicine, its benefits and risks.
 - Do not by yourself interrupt the period of treatment prescribed.
 - Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of the reach of children.

Council of Arab Health Ministers & Union of Arab Pharmacists



General Medicine

Miragel™ is a quality product manufactured by:



جمجوم فارما
Jamjoom Pharma

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