

MICREME

Miconazole Nitrate 2% w/w Vaginal Cream



What is in this leaflet

This leaflet answers some common questions about MICREME vaginal cream. It does not contain all the information available on this medicine. It does not take the place of talking to your pharmacist or doctor. All medicines have risks and benefits. Your pharmacist or doctor has weighed the risks of using MICREME vaginal cream against the benefits they expect it will have for you. If you have any concerns about using this medicine, ask your pharmacist or doctor. Keep this leaflet. You may want to read it again.

What MICREME vaginal cream is used for and how it works

MICREME vaginal cream contains the active ingredient, miconazole nitrate. It belongs to a group of medicines known as antifungals. Miconazole nitrate is a broad spectrum antifungal commonly used for the treatment of candidal fungal infections (thrush) of the vagina.

Candidiasis is an overgrowth of yeast fungus resulting in an imbalance of the natural microorganisms present in the vagina. In this condition the *Candida* organism predominates causing the symptoms of discomfort, itching, and a whitish discharge. Diabetes, obesity, illness and fatigue can increase susceptibility to the condition. Hormonal fluctuations during pregnancy, at certain times of the menstrual cycle, or due to the oral contraceptive pill, can also increase susceptibility. The balance of the vaginal environment can be altered by the prolonged use of certain medications such as antibiotics and steroids; by soaking in baths using oils, salts or harsh soaps; or by wearing too tight or synthetic clothing.

Your doctor, however, may prescribe MICREME vaginal cream for another purpose. Ask your doctor or pharmacist if you have any questions about why MICREME vaginal cream has been prescribed for you.

MICREME vaginal cream is available over the counter at a pharmacy or with a doctor's prescription.

Before you use MICREME vaginal cream

When you must not use it

Do not use MICREME vaginal cream if you have an allergy to any of the following:

- any medicine containing miconazole
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Talk to your pharmacist or doctor if you are not sure whether you should use this medicine.

Before you use it

Tell your pharmacist or doctor if you:

- have had an allergic reaction to any medicine that you have used previously to treat your current condition

- have any other medical conditions
- are allergic to any other medicines, foods, preservatives or dyes
- are pregnant, plan to become pregnant, or are breast feeding. Your pharmacist or doctor can discuss with you the risks and benefits involved.

If you have not told your pharmacist or doctor about any of the above, tell them before you use MICREME vaginal cream.

Taking other medicines

If you are taking any other medicines, including any you get without a prescription from a pharmacy, supermarket or health food shop, tell your pharmacist or doctor.

How to use MICREME vaginal cream

How much to use

Your pharmacist or doctor will tell you when to use and how often to apply MICREME vaginal cream. It is important that you use MICREME vaginal cream as directed by your pharmacist or doctor. Do not use more than the recommended dose.

Unless your pharmacist or doctor tells you otherwise, insert the contents of one full applicator (approximately 5 g) into the vagina once daily, preferably at night before bedtime, for seven consecutive days as shown below.

As well as using the cream inside the vagina, it is a good idea to smear a little around the outside of the vaginal area where itching may be a problem.

How long to use it

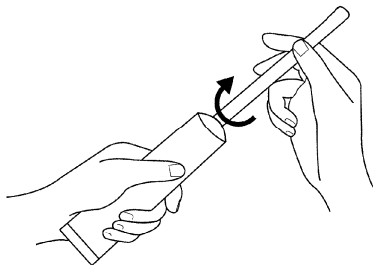
The recommended duration of treatment with MICREME vaginal cream is seven consecutive days. If your period starts while you are using MICREME vaginal cream, continue using the cream for seven consecutive days (without using tampons).

If your symptoms disappear or subside, continue using MICREME vaginal cream for seven consecutive days. If you stop your treatment before the course of the medicine is finished, your symptoms may come back.

However, if symptoms persist after the seven consecutive day treatment is completed, see your doctor or pharmacist.

Instructions for use

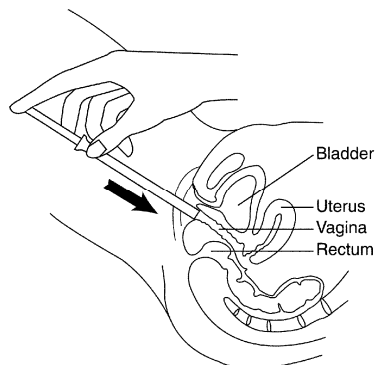
A) Filling the Applicator



1. Wash your hands thoroughly.
2. Remove the cap from the tube, and use the reverse side of the cap to pierce the tube nozzle.

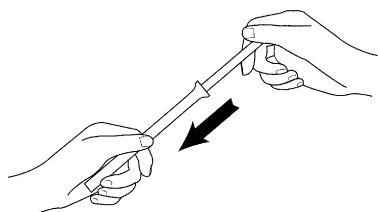
3. Screw the applicator to the tube, and fill the applicator by squeezing the bottom of the tube until the plunger is fully extended.
4. Unscrew the applicator from the tube and replace the tube cap.

B) Inserting the Applicator



1. Hold the filled applicator by the cylinder and carefully insert into the vagina, as far as is comfortably possible. This is best achieved by lying on your back with your knees bent.
2. Slowly press the plunger until it stops. This places the cream into the vagina.
3. Remove the applicator from the vagina with plunger still depressed.

C) Care of the Applicator



After each use, wash the applicator thoroughly. It can be taken apart by firmly pushing the head of the plunger up inside the cylinder. Withdraw the plunger from the cylinder. Wash the parts in warm water, with a mild detergent, and rinse thoroughly. Reassemble by pushing the plunger into the cylinder.

If you miss a dose

If you miss one or more doses of MICREME vaginal cream, apply a single dose of the cream again as soon as you remember and continue using until the course of treatment is completed. Do not apply two doses at once to make up for a missed dose.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

While you are using MICREME vaginal cream

Tell all doctors, dentists and pharmacists who are treating you that you are using MICREME vaginal cream.

Tell your doctor or pharmacist if you become pregnant while using MICREME vaginal cream.

Do not use MICREME to treat any other condition unless your doctor tells you to.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

MICREME vaginal cream should only be used vaginally. It should not be eaten or swallowed.

Keep away from eyes and mouth. If you get any of the cream into your eyes rinse immediately with large amounts of cool tap water with your eyes open.

MICREME vaginal cream should not be used in combination with rubber products such as condoms and diaphragms, as this medicine may destroy the rubber. The effectiveness of vaginal spermicides as a birth control method may also be reduced. It is therefore recommended that condoms, diaphragms and spermicides should not be used in combination with MICREME vaginal cream, as these forms of contraception may fail in which case pregnancy or sexually transmitted disease cannot be prevented.

Do not use tampons during the course of treatment.

If you are sexually active, ask your pharmacist or doctor if your partner should also be treated.

Strict personal hygiene must be observed to avoid the possibility of re-infection. Wash your hands thoroughly before and after inserting the applicator into the vagina. Underwear and towels (including flannels) should be changed daily. Do not share your towel(s) with anyone else.

Avoid wearing tight clothing and avoid all medicated and perfumed bath additives, soaps, etc.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are using MICREME vaginal cream.

All medicines can have some unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Tell your pharmacist or doctor if you notice any of the following skin side effects and they worry you:

- irritation
- itching
- burning sensation.

These are the more common side effects of MICREME vaginal cream. They are usually mild and are more common at the start of treatment. MICREME vaginal cream is generally well tolerated after local application.

Tell your doctor immediately if you notice any of the following skin side effects:

- sudden or severe itching and/or irritation
- sudden or severe skin rash or hives.

These side effects may indicate an allergy to the medicine. You may need urgent medical attention.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your pharmacist or doctor.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

In case of swallowing

You should only use MICREME vaginal cream as directed by your pharmacist or doctor. MICREME vaginal cream should not be eaten or swallowed.

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you have eaten or swallowed MICREME vaginal cream, or if you think anyone else may have eaten or swallowed MICREME vaginal cream by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of MICREME vaginal cream with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Do not use this medicine after the expiry date shown on the pack or if the packaging shows signs of tampering.

Store below 25°C. Keep out of reach of children. Avoid exposure to heat, moisture and light.

Do not use this medicine if the cream does not appear white in colour or has liquefied.

Disposal

If you do not use MICREME vaginal cream, it has passed the expiry date, or your doctor or pharmacist tells you to stop using this medicine, ask your pharmacist what to do with the remaining medicine.

List of other ingredients

Your medicine is in the form of a smooth white cream supplied in an aluminium tube. Each tube of MICREME vaginal cream contains 40 g of cream with a 5 g applicator.

Each gram of MICREME 2% w/w vaginal cream contains 20 mg of the active ingredient, miconazole nitrate.

MICREME vaginal cream also contains benzyl alcohol, polysorbate, cetyl esters wax, cetostearyl alcohol, sorbitan monostearate, octyldodecanol and purified water.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183, Ellerslie, Auckland.
Freephone: 0800 579 811

Date of information

2 February 2009
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