

NEW ZEALAND CONSUMER MEDICINE INFORMATION

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 available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor or pharmacist has weighed the risks of you taking MICREME vaginal cream against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What MICREME Vaginal Cream is used for

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 candida fungal infections (thrush) of the vagina.

Candidiasis is an overgrowth of Candida 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 this 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.

Ask your pharmacist or doctor if you have any questions about why this medicine has been recommended for you.

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 medicine containing miconazole or miconazole nitrate
- other 'imidazole' medicines e.g. clotrimazole, econazole or ketoconazole
- any of the ingredients listed at the end of this leaflet.

Some of the 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.

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

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to use it

Tell your doctor or pharmacist if:

- you have allergies to any other medicines, foods, preservatives or dyes
- you have or have had any other medical conditions.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor or pharmacist can discuss with you the risks and benefits involved.

If you have not told your doctor or pharmacist about any of the above, tell him or her before you start using MICREME vaginal cream.

Taking other medicines

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

Some medicines and MICREME vaginal cream may interfere with each other. These include:

- oral anticoagulants such as warfarin, used to prevent blood clots

- simvastatin and lovastatin used to lower cholesterol.
- calcium channel blockers such as dihydropyridines and verapamil used for high blood pressure
- oral medicines used to treat diabetes
- phenytoin, a medicine used for epilepsy.

These medicines may be affected by MICREME vaginal cream or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use MICREME Vaginal Cream

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box or tube, ask your doctor or pharmacist for help.

How much to use and when to use it

Your pharmacist or doctor will tell you when and how often to use 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 grams) into the vagina once daily, preferably at night before bedtime, for seven consecutive days, as shown in the diagrams below.

As well as using the cream inside the vagina, it is a good idea to smear some MICREME vaginal cream 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).

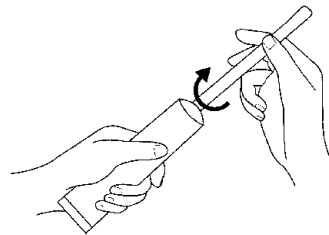
If your symptoms disappear or subside, continue using MICREME vaginal cream for seven consecutive days. If you stop your treatment before the course of the medicine is finished, your symptoms may come back.

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

Instructions for use

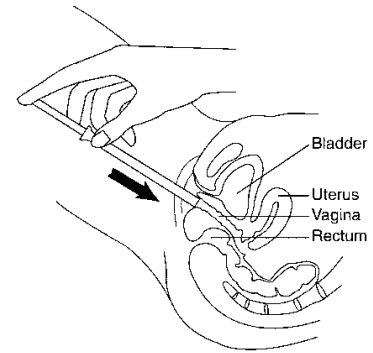
A) Filling the Applicator

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.



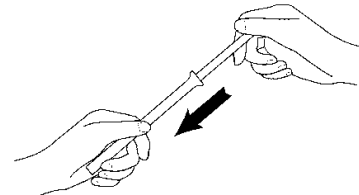
3. Screw the applicator to the tube, and fill the applicator by squeezing the bottom of the tube until the plunger is fully extended.
4. Unscrew the applicator from the tube and replace the tube cap.

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 are not sure what to do, ask your doctor or pharmacist.

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

In case of swallowing

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

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or 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.

While you are using MICREME Vaginal Cream

Things you must do

Tell any doctors, dentists, and pharmacists who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

If you become pregnant while using this medicine, tell your doctor immediately.

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

Things you must not do

Do not use MICREME vaginal cream to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

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

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

Do not use tampons during the course of treatment.

Things to be careful of

MICREME vaginal cream should not be used in combination with rubber products such as condoms and diaphragms, as the cream 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.

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

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

Most people do not experience any side effects when they use MICREME vaginal cream correctly, but it may have unwanted side effects in some people.

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 rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing or swallowing.

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.

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

After using MICREME Vaginal Cream

Storage

Keep your MICREME vaginal cream in a cool dry place where the temperature stays below 25°C.

Do not store MICREME vaginal cream or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Do not use MICREME vaginal cream if the cream does not appear white in colour or has liquefied.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Date of Information

28 July 2016
(Based on datasheet dated 28 July 2016)

Product description

What it looks like

MICREME vaginal cream is a smooth, white cream supplied in an aluminium tube. Each tube of MICREME vaginal cream contains 40 grams of cream and comes with a 5 gram applicator.

Ingredients

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

- octyldodecanol
- cetostearyl alcohol
- cetyl esters wax
- sorbitan monostearate
- polysorbate 60
- benzyl alcohol
- 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.

Telephone: 0800 168 169