NEW ZEALAND CONSUMER MEDICINE INFORMATION

MICREME H

Topical Cream

Miconazole Nitrate 2 % w/w; Hydrocortisone 1 % w/w

What is in this leaflet

This leaflet answers some common questions about MICREME H.

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 pharmacist or doctor has weighed the risks of you using MICREME H against the benefits they expect it will have for you.

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

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

What MICREME H is used for

MICREME H is used on the skin to treat inflamed skin conditions such as tinea, athlete's foot, ringworm and thrush infections of the skin.

MICREME H is a broad-spectrum anti-fungal and anti-inflammatory cream.

MICREME H contains two active ingredients: miconazole nitrate and hydrocortisone. Miconazole nitrate acts against fungal organisms and certain bacteria to help treat infections, while hydrocortisone reduces the irritation and redness of inflamed skin.

Your doctor may have prescribed it for another reason.

MICREME H is available over the counter at a pharmacy or on a prescription from your doctor. Ask your doctor or pharmacist if you have any questions about this medicine.

Before you use MICREME H

Do not use MICREME H for:

- viral disease of the skin, for example chickenpox, shingles and cold sores
- any skin conditions caused by tubercule or tuberculosis bacteria or syphilis
- bacterial infections.

Do not use MICREME H if you have an allergy to:

- any medicine containing miconazole/miconazole nitrate, or other imidazole derivatives
- any medicine containing
 hydrocortisone
- 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 MICREME H 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.

Do not use MICREME H on children under 2 years unless your doctor or pharmacist tells you to.



If you are not sure whether you should start using 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
- you have an existing skin infection
- you have cuts or abrasions near the site of treatment.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breastfeeding.

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 them before you start using MICREME H.

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 H may interfere with each other. These include:

 anticoagulants, medicines used to prevent blood clots such as warfarin.

These medicines may be affected by MICREME H 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 H

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.

Instructions for use

Each tube of MICREME H is sealed. Use the cap to pierce the seal.

Before applying the cream

Wash the infected skin and dry it well each time you use the cream.

As many skin conditions are infectious, you should keep a towel and a flannel for your own use so that you do not infect anyone else.

After applying the cream

Unless the infected skin is on your hands, wash your hands carefully to avoid spreading the infection to other parts of the body or to other people.

Similarly, clothing which comes into contact with the infected areas should be changed and washed frequently.

How much to use

Your pharmacist or doctor will tell you when and how often to apply MICREME H to the affected area of skin.

Unless your pharmacist or doctor tells you otherwise, MICREME H should be applied sparingly once or twice daily to the affected areas of your body and rubbed gently with a finger into the skin. It is important that you apply MICREME H exactly as directed by your pharmacist or doctor. Do not use more than the recommended dose.

How long to use it

Regular application of MICREME H is essential for successful treatment. If you use it less often than you should, it may not work as well and your skin problem may not improve. Using it more often than you should may not improve your skin problems any faster and may cause or increase side effects.

Once the inflammation has subsided continue treatment with an anti-fungal agent without hydrocortisone, such as a miconazole-containing cream. Continue treatment with the antifungal agent until the symptoms completely disappear.

Do not use MICREME H for longer than 14 days, unless your pharmacist or doctor tells you to.

If your condition does not improve after 7 days of treatment with MICREME H, consult with your doctor.

If you forget to use it

If you miss a dose of MICREME H, apply a single dose of the cream as soon as you remember and continue using the cream until the course of treatment is completed.

Do not apply a double dose to make up for the dose that you missed.

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.

While you are using MICREME H

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are using MICREME H. If you are about to be started on any new medicine, tell your doctor and pharmacist that you are using MICREME H.

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

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

If you are going to have any blood tests, tell your doctor that you are using MICREME H.

MICREME H should only be used on the skin. 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.

Areas such as the armpits and the feet, especially between the toes, should be dried thoroughly after washing.

Things you must not do

Do not use MICREME H 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.

Do not use MICREME H in or near the eyes.

Do not use MICREME H for acne.

Do not use MICREME H on your face, unless your doctor or pharmacist tells you to.

Things to be careful of

Do not use MICREME H under dressings (including waterproof bandages) or under a baby's nappy, unless your doctor or pharmacist tells you to.

Do not use MICREME H on large areas of skin, unless your doctor or pharmacist tells you to.

MICREME H can cause thinning of the skin. Therefore, MICREME

H should be used sparingly and for short periods of time, unless advised by your doctor or pharmacist.

MICREME H can damage certain synthetic materials. Therefore, it is recommended that cotton be worn where clothing contacts the affected area.

In case of overdose

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

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have eaten or swallowed MICREME H. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of MICREME H with you if you can.

Side effects

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

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 H correctly, but it may have unwanted side effects in some people.

Tell your doctor or pharmacist as soon as possible if you notice any of the following and they worry you:

- skin irritation
- itching or itchy rash
- red or inflamed skin
- pale areas of skin
- burning skin sensation
- irritability
- blurred vision.

If your skin condition gets worse during treatment, stop using MICREME H and tell your pharmacist or doctor as soon as possible.

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.

Tell your doctor or pharmacist as soon as possible if you notice any of the following after you stop using MICREME H. Some people may experience a withdrawal reaction after stopping treatment with MICREME H:

- redness of the skin which can extend beyond the initial area treated
- a burning or stinging sensation
- intense itching
- peeling of the skin
- oozing open sores.

Tell your doctor or pharmacist as soon as possible if you should suffer from any side effects or undesirable effects.

Other side effects not listed above may occur in some people.

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 H

Storage

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

Do not store MICREME H 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 H 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-anda half metres above the ground is a good place to store medicines.

Disposal

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

Product description

What it looks like

MICREME H is a smooth, white cream supplied in an aluminium tube. Each tube of MICREME H contains 15 grams of cream.

Ingredients

Active ingredients:

MICREME H contains miconazole nitrate and hydrocortisone as the active ingredients. Each gram of MICREME H contains 20 mg of miconazole nitrate and 10 mg of hydrocortisone.

Inactive ingredients: MICREME H 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

MICREME H is supplied in New Zealand by:

Viatris Ltd PO Box 11-183 Ellerslie AUCKLAND <u>www.viatris.co.nz</u> Telephone 0800 168 169

Date of Preparation

2 June 2022 (Based on datasheet dated 2 June 2022)