

PACKAGE LEAFLET:
INFORMATION FOR THE USER
Clotrimazole Cream 1%

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.
- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Clotrimazole is and what it is used for

The active substance is clotrimazole. Clotrimazole belongs to a group of medicines called imidazoles and is an antifungal agent which fights the cause of fungal skin infections. Clotrimazole is used to treat fungal skin infections such as ringworm, athlete's foot, fungal nappy rash and fungal sweat rash. It is also used to relieve irritation of the vulva (external thrush) or the end of the penis, which may be associated with thrush. When Clotrimazole is applied to the infected area of skin it works by destroying the fungus or yeast which has caused the infection.

If you are unsure whether you (or your baby if treating nappy rash) have one of these fungal skin infections, seek the advice of your doctor or pharmacist.

2. What you need to know before you use Clotrimazole

Do not use Clotrimazole:

- if you (or your baby if treating nappy rash) are allergic to clotrimazole or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Clotrimazole if you have used a cream containing clotrimazole or a similar medicine before and suffered an allergic or unpleasant skin reaction. This may have

been a skin rash or itching in the area the cream was applied. Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Other medicines and Clotrimazole

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. Clotrimazole is not known to interact with any other medicines.

As with other creams, Clotrimazole may reduce the effectiveness of rubber contraceptives, such as condoms or diaphragms. Consequently, if you are using this cream on the vulva or penis, you should use alternative precautions for at least five days after using this product.

Pregnancy and breastfeeding

Clotrimazole Cream 1% can be used in pregnancy and breastfeeding. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, tell your doctor, midwife or pharmacist before using Clotrimazole. If you have informed your doctor or midwife already, follow his/her instructions carefully.

Driving and using machines

Clotrimazole will not affect your ability to drive or operate machinery.

Clotrimazole contains cetostearyl alcohol

This medicine contains cetostearyl alcohol which may cause local skin reactions (e.g. rash, itching or redness).

Clotrimazole contains benzyl alcohol

This medicine contains benzyl alcohol which may cause mild local irritation.

3. How to use Clotrimazole

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If you purchased this product without a prescription, follow these directions closely.

- Before use, pierce the tube seal by inverting the cap over the end of the tube and press.
- If the feet are infected, they should be washed and dried thoroughly, especially between the toes, before applying the cream.
- Clotrimazole should be applied thinly and evenly to the affected areas, two or three times daily and rubbed in gently.
- A strip of cream (½ cm long) is enough to treat an area of about the size of the hand.
- The duration of the treatment depends upon the type of infection. Use the cream for at least two weeks for candida (thrush) infections or at least one month for other infections.

- If you have athlete's foot, it may help to use an antifungal dusting powder as well. Ask your doctor or pharmacist to recommend one.

The symptoms of skin infection such as itching or soreness, should improve within a few days of treatment although signs such as redness and scaling may take longer to disappear. If symptoms persist, consult your doctor.

Clotrimazole is for external use only.

Do not put the cream in your mouth or swallow it.

If the cream is swallowed accidentally, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

If you accidentally get cream in your eyes or mouth, wash immediately with water and contact your doctor.

If you forget to use Clotrimazole

Apply the cream as soon as possible, then continue the rest of your treatment as usual.

If you stop using Clotrimazole

Do not suddenly stop using Clotrimazole as this may cause the symptoms of the infection to return.

You can help the treatment to work if you follow these simple self-help tips:

- Although the infected area will itch, try not to scratch. Scratching will damage the surface of the skin and cause the infection to spread further.
- Keep the affected skin areas clean.
- Pay particular attention to drying the skin, but avoid excessive rubbing.
- Do not share towels, bath mats, etc. with other people as you could spread the infection to them.
- Always wash your hands after treating the infection to prevent it from spreading.

If you have athlete's foot:

- Remember to dry the skin between the toes thoroughly.
- Wash your socks, stockings and tights thoroughly in hot water to remove any shed skin or fungal spores.
- Change your footwear daily if possible.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the cream. If you or your baby are allergic, a reaction will occur soon after you start using it. If you or your baby experience an allergic reaction, stop using Clotrimazole and tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital. Signs of an allergic reaction may include:

- Rash
- Swallowing or breathing problems
- Swelling of the lips, face, throat or tongue

- Weakness, feeling dizzy or faint
- Nausea

After you apply the cream you might experience:

- Itching, rash, blisters, burning, discomfort, swelling, irritation, pins and needles, redness or peeling of skin. This may mean that you are allergic to the cream.

Reporting of side effects

If you or your baby gets any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clotrimazole

Keep this medicine out of the sight and reach of children.

Store in a cool dry place.

Do not use this cream after the expiry date which is stated on the carton after EXP.

The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Clotrimazole contains

The active substance is clotrimazole. Each gram of cream contains 10 mg of clotrimazole (i.e. 1% w/w).

The other ingredients are benzyl alcohol (see section 2 "Clotrimazole contains benzyl alcohol"), polysorbate 60, cetyl esters wax, cetostearyl alcohol (see section 2 "Clotrimazole contains cetostearyl alcohol"), octyldodecanol, sorbitan monostearate and purified water.

What Clotrimazole looks like and contents of the pack

Clotrimazole Cream 1% is a smooth white cream and is available in tubes of 20g or 50g. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan
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Manufacturer

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