

Clomazol 1% (10 mg/g) vaginal cream, 6-day treatment

What is in this leaflet

Please read this leaflet carefully before you start using Clomazol 1% vaginal cream.

This leaflet answers some common questions about Clomazol 1% 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 pharmacist has weighed the risks of you using Clomazol 1% vaginal cream 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 Clomazol 1% vaginal cream is used for

Clomazol 1% vaginal cream is used to treat a fungal infection in the vagina and vulval area (thrush).

This medicine belongs to a group of medicines called azole antifungals.

What is vaginal thrush?

Candida albicans is a yeast fungus that can multiply rapidly and cause symptoms in the vagina when other micro-organisms aren't present in a normal balance.

Some situations which can increase susceptibility to thrush are:

- diabetes
- obesity
- illness
- fatigue
- hormonal fluctuations (pregnancy, menstrual cycle, oral contraceptive pill, HRT [hormone replacement therapy])
- prolonged use of antibiotics or steroids

Thrush may cause the following symptoms:

- vaginal itching
- vaginal soreness
- a white odourless discharge from the vagina (like cottage cheese)
- pain during intercourse

The symptoms below are **not** usually signs of thrush:

- abnormal or irregular vaginal bleeding

- blood stained discharge
- vulva or vaginal sores, ulcers or blisters
- lower abdominal pain
- pain when passing urine
- fever or chills
- foul smelling and/or unusual coloured discharge

See your doctor if you experience any of the above symptoms.

Ask your doctor or pharmacist if you have any questions about whether this medicine is suitable for you.

This medicine is available without a doctor's prescription, only through your pharmacist.

Before you use Clomazol 1% vaginal cream

When you must not use it

Do not use Clomazol 1% vaginal cream if you have an allergy to:

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

Some of the symptoms of an allergic reaction may include swelling of the parts of the body to which treatment has been applied; 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 using this medicine, talk to your doctor or pharmacist.

Before you start to use it

See your doctor if:

- you are unsure whether you have thrush or this is the first time you have had thrush (see *What is vaginal thrush?*)
- you are under the age of 18 years or over the age of 60 years
- you have had 3 or more infections in the last 6 months
- your symptoms include pain, fever or a foul smelling, unusual coloured or blood stained discharge
- you have allergies to any other topical treatments

Tell your doctor if you are pregnant or think you might be

You should see your doctor if you suspect you have thrush in the first three months of your pregnancy. Your doctor can discuss with you the risks and benefits involved with treatment.

Tell your doctor if you are breast-feeding and want to use this treatment

This medicine may be excreted in breast milk. Breast-feeding should be discontinued during treatment with clomazol 1% vaginal cream.

Tell your doctor if you are diabetic

Thrush in diabetics can mean that your blood sugar levels are not well controlled. Your doctor will be able to check this for you and advise treatment.

If you have not told your doctor about any of the above, do so before you start using Clomazol 1% vaginal cream.

Taking other medicines

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

Tell your doctor or pharmacist if you are taking tacrolimus or sirolimus, medicines used to prevent organ transplant rejection or to treat certain problems with the immune system.

You should also tell any health professional who is prescribing a new medication for you that you are using Clomazol 1% vaginal cream.

How to use Clomazol 1% 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 below, or on the box, ask your doctor or pharmacist for help.

How to use it

Wash your hands thoroughly before handling the cream or using the applicator.

To avoid the possibility of re-infection, strict personal hygiene must be observed.

The cream should preferably be inserted in the evening, just before bed time, with the use of an applicator. Using it before you go to sleep will have the best effect.

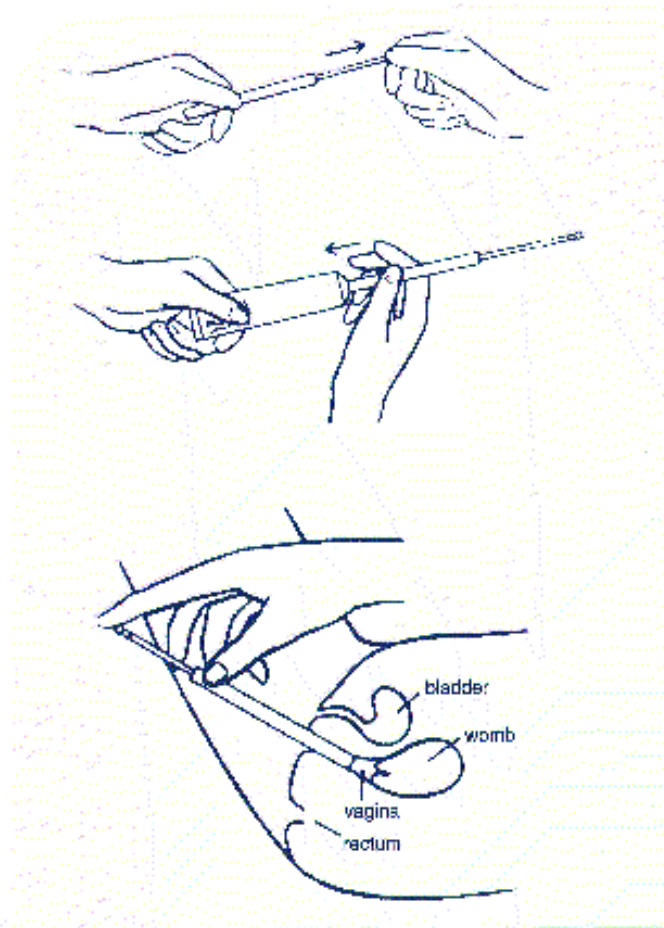
Use a new applicator for each nightly dose.

Loading an applicator

1. Wash your hands thoroughly
2. Pull out the plunger of the disposable applicator until it stops
3. Open the Clomazol 1% vaginal cream tube. Attach the applicator to the tube and hold it firmly pressed against the tube
4. Squeeze the cream tube until the applicator is full
5. Remove the tube of cream and replace the cap

Inserting the applicator

1. Carefully insert the end of the applicator containing the cream as gently and deeply into the vagina as possible. This is best achieved when lying on your back with your knees bent.
2. Hold the applicator in position and slowly push the plunger with the forefinger until it stops. This places the cream in the vagina.
3. Remove the applicator from the vagina and dispose of the applicator.

***How long to use it***

Continue using the cream for 6 consecutive nights.

This treatment helps to relieve your condition. It is important to keep using it until the fungal infection is gone.

If you miss a dose, continue with the next dose as soon as you remember, or the next evening.

Continue using the cream until the course is finished. The 35 g tube contains enough cream for 6 doses.

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

While you are using Clomazol 1% vaginal cream

Things you must do

Discontinue treatment and tell your doctor or pharmacist if you develop a local reaction to this product.

See your doctor if the symptoms do not improve within 4 days or if the problem returns within 2 months.

Things you must not do

Do not use Clomazol 1% vaginal cream to treat any other complaints unless your doctor tells you to.

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

Do not stop using this medicine until you have completed the course.
If you stop taking it suddenly, your condition may worsen.

Things to be careful of

Preferably the treatment should be timed to avoid the menstrual period.

This will allow the treatment to be most effective. Ask your doctor if you have questions about this.

Clomazol 1% vaginal cream may reduce the effectiveness and safety of latex products such as condoms and diaphragms if it comes into contact with them.

Therefore you should prevent Clomazol 1% vaginal cream from coming into contact with these products. If Clomazol 1% vaginal cream does accidentally come into contact with a condom or diaphragm, replace the condom or diaphragm before using it as contraception.

Things that may help to resolve Thrush

Some self-help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

- blot with toilet paper after urinating (instead of wiping back to front).
- change underwear, night attire, towels and linen daily.

Avoid where possible:

- perfumed toilet paper
- fragrant soaps and bath oils
- wearing tight or synthetic clothing
- douches or vaginal deodorants
- soaking in baths

Side Effects

Tell your doctor or pharmacist if you experience discomfort while you are using Clomazol 1% vaginal cream.

This medicine helps most people with thrush but it may have unwanted side effects in a few people. 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.

Do not be alarmed by the following side effects. You may not experience any of them.

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

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

- skin reaction to the cream (stinging, redness, blistering, peeling, swelling, itching)
- pain in the abdomen or pelvic area

Tell your doctor immediately or go to your nearest Accident and Emergency centre if you experience any of the following:

- rash
- swallowing or breathing problems
- swelling of your lips, face, throat or tongue
- nausea, weakness, feeling dizzy or faint

Any of the above may be signs of an allergic reaction. Your doctor or pharmacist may recommend you discontinue treatment if you experience these effects.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

After using Clomazol 1% vaginal cream

Storage

Keep your cream in the tube until it is time to use it.

If you take the cream out of the tube it may not keep well.

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

Keep the treatment 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.

Expiry

The expiry date is marked on the end panel of the carton and is also printed on the crimp at the end of the tube.

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.

Discard the medicine out of the reach of children.

Product description

What it looks like

Clomazol 1% vaginal cream is a white opaque cream presented in a screw-cap tube containing 35 g of cream.

The package also contains 6 disposable plastic applicators.

Ingredients

Active ingredient:

Clomazol 1% vaginal cream contains 10 mg of clotrimazole in each gram of cream. It also contains:

Inactive ingredients:

- glyceryl monostearate
 - cetostearyl alcohol
 - benzyl alcohol
 - disodium edetate dihydrate
 - cetomacrogol 1000
 - propylene glycol
 - liquid paraffin
 - dimeticone
 - white soft paraffin
 - purified water
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Sponsor Details

Clomazol 1% vaginal cream is distributed in New Zealand by:

Multichem NZ Ltd
Private Bag 93527
Takapuna
Auckland
Telephone: (09) 488 0330

Date of Preparation

This leaflet was prepared on 08 October 2019.