

Canesten®

10% w/w Vaginal Cream

Clotrimazole



Read all of this leaflet carefully because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not give it to anyone else under any circumstances.
- If you have any unusual effects after using this product, tell your doctor.

IN THIS LEAFLET

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1. WHAT IS CANESTEN® VAGINAL CREAM AND WHAT IS IT USED FOR?

Canesten Vaginal Cream is a single application, full course treatment for vaginal thrush (candidiasis). It is a soothing intravaginal cream in a pre-filled applicator for treatment at the site of infection.

The active substance in Canesten Vaginal Cream is clotrimazole. Clotrimazole belongs to a group of medicines called azoles and is an antifungal agent which fights the cause of infections such as vaginal thrush.

2. BEFORE YOU USE CANESTEN® VAGINAL CREAM

Do not use Canesten® Vaginal Cream:

- If you are allergic (hypersensitive) to clotrimazole or any of the other ingredients, including cetostearyl alcohol, of Canesten Vaginal Cream (see Section 6. Further Information).
- During your period as it may be less effective.

Important information about some of the ingredients:

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

Special precautions:

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

Do not use tampons, intravaginal douches, spermicides or other vaginal products while using this product.

Avoid vaginal intercourse while you have thrush and during use of this product because your partner could become infected.

Using other medicines:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Inform your doctor if you are taking tacrolimus or sirolimus (used to reduce the immune response to prevent rejection after an organ transplant).

Pregnancy and breast-feeding:

If you are pregnant, breast-feeding or trying for a baby, tell your doctor or midwife before using Canesten Vaginal Cream.

If you have informed your doctor or midwife already, follow his/her instructions carefully.

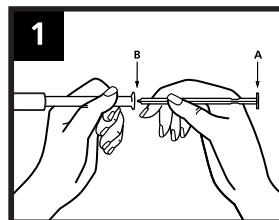
To treat internal thrush, your doctor may recommend that you use a treatment that can be inserted in the vagina without the help of an applicator, such as a clotrimazole pessary

3. HOW TO USE CANESTEN® VAGINAL CREAM

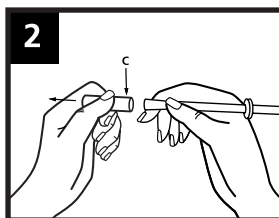
Unless directed otherwise by your doctor, the cream should be inserted as high as possible into the vagina, preferably before going to sleep at night for convenient and comfortable treatment.

Wash your hands before removing the foil from the blister pack and again afterwards when you have used the applicator.

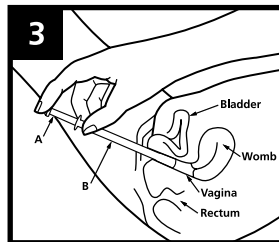
1. Remove the applicator from the packaging. Keeping the cap in place, insert the tip of plunger A into the applicator B (approximately 1cm).



2. Twist and pull to remove the cap C. Be careful not to press the plunger in any further before you have inserted the applicator into the vagina. This will avoid wasting any cream.



3. Carefully put the applicator as deep as is comfortable into the vagina (this is easiest when lying on your back with your knees bent up). Holding the applicator in place, slowly press the plunger until it stops so that the pre-measured dose of cream is deposited into the vagina.



4. Remove the applicator. Dispose of the applicator in a safe place, out of the reach of children. The applicator cannot be flushed down the toilet.

The cream is deposited in the vagina, but it is quite common to notice a slight discharge after using the cream and therefore it may be helpful to wear a panty liner. This does not mean that the treatment has not worked.

The symptoms of thrush should disappear within three days of treatment. If no improvement is seen after seven days you must tell your doctor.

Canesten® Vaginal Cream is for use in the vagina 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Canesten Vaginal Cream can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the cream.

If you are allergic, a reaction will occur soon after you have used the medicine. If you experience an allergic reaction or the redness, burning, pain, itching or swelling get worse, stop using this product 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 your lips, face, throat or tongue.
- Weakness, feeling dizzy or faint.
- Nausea.

After you apply Canesten Vaginal Cream you might experience:

- Itching, rash, swelling, redness, discomfort, burning, irritation, vaginal peeling or bleeding.
- Pain in the abdomen or pelvic area.

If you experience any of the above effects, tell your doctor immediately.

Reporting of side effects

If you get 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

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CANESTEN® VAGINAL CREAM

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

Do not store above 25°C.

Do not use Canesten Vaginal Cream after the expiry date which is stated at one end of the carton, on the applicator and on the applicator foil wrapping. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Canesten® Vaginal Cream contains:

- The active substance is clotrimazole at a strength of 500mg (10% w/w).
- The other ingredients are benzyl alcohol, polysorbate 60, sorbitan stearate, cetostearyl alcohol, isopropyl myristate, cetyl palmitate and water.

See Section 2 'Do not use' and 'Important information about some of the ingredients' for cetostearyl alcohol advice.

What Canesten® Vaginal Cream looks like and contents of the pack:

Canesten Vaginal Cream is available in single-dose packs containing 5g of white cream in a pre-filled applicator.

Marketing Authorisation Holder:

Bayer plc, 400 South Oak Way, Reading, RG2 6AD, UK.

Manufacturer:

Kern Pharma S.L.
Poligon Industrial Colon II, Calle Venus 72
08228 Terrassa, Barcelona, Spain.

Remember: This medicine has been prescribed for you. Do not give it to anyone else under any circumstances.

If you have any doubts about using Canesten® Vaginal Cream correctly, seek the advice of your doctor or pharmacist.

Further information about vaginal thrush:

Vaginal thrush (candidiasis) is a common infection that most women suffer from at some time in their lives and is not caused by lack of personal hygiene.

Thrush is caused by a yeast (fungus) called Candida which lives harmlessly in the vagina and other parts of the body, without you even noticing it. However, the natural balance that keeps Candida under control can be upset by many factors such as hormonal changes (menstruation, contraceptive pill, pregnancy, menopause), poor health, antibiotics, perfumed soaps, bath additives and tight clothing.

If the natural pH balance is altered, the level of yeast increases and can develop into a thrush infection causing any of the following symptoms: persistent burning and/or itching around the vagina and vulva, redness, swelling and soreness of the tissues of the vagina and vulva and a whitish, odourless discharge from the vagina. Not everybody who has thrush has all these symptoms; you may have only one of them.

How to avoid future recurrences:

- ✓ Wear cotton knickers and loose clothing.
- ✓ Wash daily.
- ✓ After going to the toilet, wipe yourself from the front to back as a thrush infection may be transferred from the bowel.
- ✓ Change your sanitary protection regularly.
- ✗ Try to avoid wearing tights, nylon knickers and close fitting jeans.
- ✗ Try to avoid washing with perfumed soaps or using vaginal deodorants.
- ✗ Do not wash or rub yourself hard with sponges or flannels and avoid hot baths with strong perfumed oils.

If you are still worried or have any questions about the symptoms or the treatment of thrush, do not hesitate to ask your doctor or pharmacist for advice.

For UK residents only: if you have any questions or would like more information, call our Canesten Advice Line on 0845 758 5030. Calls charged at local rate.

This leaflet was last revised in October 2017.

Canesten is a registered trademark of Bayer AG, Germany.

Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.

