

Canesten®

Combi Soft Gel Pessary & External Cream

500mg vaginal capsule & 2% w/w 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.

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1. WHAT IS CANESTEN® COMBI AND WHAT IS IT USED FOR?

Canesten Combi Soft Gel Pessary & External Cream is a full course of treatment for vaginal thrush (candidiasis) because it treats both the internal cause and external symptoms.

Some women suffer from recurrent attacks of thrush. To reduce the frequency of these attacks, the sexual partner's penis can be treated with this cream to prevent re-infection, even if they have no symptoms of thrush.

The active substance in Canesten Combi Soft Gel Pessary & External 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® COMBI

Do not use Canesten® Combi Soft Gel Pessary & External Cream:

- If you are allergic (hypersensitive) to clotrimazole or any of the other ingredients, including cetostearyl alcohol, of Canesten Combi Soft Gel Pessary & External Cream (see Section 6. Further Information).

Important information about some of the ingredients:

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

Special precautions:

As with other creams and pessaries, 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.

Do not use this product during your period as it may be less effective.

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 Combi Soft Gel Pessary & External 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 the pessary without the help of an applicator.

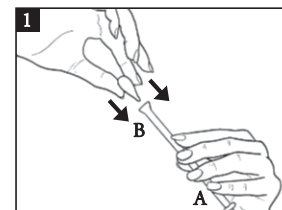
3. HOW TO USE CANESTEN® COMBI

The Soft Gel Pessary:

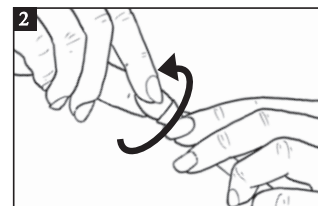
Unless directed otherwise by your doctor, the Soft Gel Pessary should be inserted as high as possible into the vagina, preferably before going to sleep at night for convenient and comfortable treatment.

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

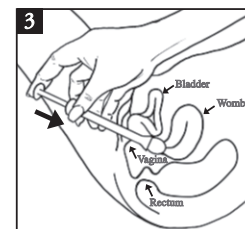
1. Remove the applicator from the packaging. Pull out the plunger A until it stops. Remove the pessary from the foil blister pack and place firmly into the applicator B.



2. Fix the Soft Gel Pessary firmly into the designated holder of the applicator B, by a light twist. The pessary fits tightly into the applicator.



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 pessary 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.

Since the pessary dissolves in the vagina, it may be helpful to wear a panty liner.

The Cream:

Women:

Before use, pierce the tube seal by inverting the cap over the end of the tube and press.

To treat the itching and soreness of the vulva, the cream should be thinly and evenly applied to the area around the entrance of the vagina, 2 or 3 times a day and smoothed in gently. Treatment should be continued until the symptoms of the infection disappear.

The symptoms of thrush should disappear within three days of treatment. If no improvement is seen after seven days you must tell your doctor. If the infection returns after seven days you may use one further treatment, but if you have more than two infections within six months you should see your doctor.

Treating your sexual partner:

If your sexual partner is treated with this cream, the cream should be applied to the end of the penis 2 or 3 times a day for up to two weeks.

Canesten Combi Soft Gel Pessary & External Cream is not recommended for use in children under 16 years old.

The Soft Gel Pessary is for use in the vagina only. The cream is for external use only:

Do not put the pessary or cream in your mouth or swallow them.

If the pessary or cream are 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 Combi Soft Gel Pessary & External Cream can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the pessary or 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 use the pessary you might experience:

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

After you apply the cream you might experience:

- Itching, rash, blisters, burning, discomfort, swelling, redness, irritation or peeling of skin.

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® COMBI

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

This product should be stored in the original carton in a dry place in order to protect from moisture.

Do not store above 30°C.

Do not use the pessary or cream after the expiry date which is stated at one end of the carton, on the foil blister strip of the pessary and on the end of the tube of cream. 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® Combi Soft Gel Pessary & External Cream contains:

Soft Gel Pessary:

- The active substance is clotrimazole at a strength of 500mg.
- The other ingredients are white soft paraffin, liquid paraffin, gelatin, glycerol, water, titanium dioxide (E171), quinoline yellow (E104), sunset yellow (E110), lecithin, medium-chain triglycerides.

Cream:

- The active substance is clotrimazole at a strength of 2% w/w.
 - The other ingredients are benzyl alcohol, polysorbate 60, sorbitan stearate, cetyl palmitate, cetostearyl alcohol, octyldodecanol and purified water.
- See Section 2 'Do not use' and 'Important information about some of the ingredients' for cetostearyl alcohol advice.

What Canesten® Combi Soft Gel Pessary & External Cream looks like and contents of the pack:

Canesten Combi Soft Gel Pessary & External Cream contains a full course of treatment, which consists of a single yellow teardrop-shaped soft vaginal capsule held inside a foil blister pack, one applicator for insertion of the pessary into the vagina and one 10g tube of white cream.

Marketing Authorisation Holder:

Bayer plc, Consumer Care Division,
Bayer House, Strawberry Hill
Newbury, Berkshire RG14 1JA, UK.

Manufacturer:

GP Grenzach Produktions GmbH,
79639 Grenzach-Wyhlen, Germany.

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® Combi Soft Gel Pessary & External 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 June 2014.

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.



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