

Patient Information Leaflet

Canesten® Combi Pessary and Cream

clotrimazole

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

This medicine is available without prescription. However, you still need to use Canesten Combi Pessary & Cream carefully to get the best results from it.

- 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 in 7 days.
- If you have any unusual effects after using this product, tell your doctor or pharmacist.

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1. What is Canesten Combi and what is it used for?

Canesten Combi Pessary & Cream is a complete treatment for vaginal thrush because it treats both the internal cause and external symptoms.

Only use this product if you have been previously diagnosed by your doctor as having vaginal thrush.

The active substance in Canesten Combi Pessary & 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.

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 reinfection, even if they have no symptoms of thrush.

2. Before you use Canesten Combi

Do not use Canesten Combi Pessary & Cream:

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

Before using Canesten Combi Pessary & Cream, you should see your doctor if:

- You are unsure whether you have thrush or this is the first time you have had these symptoms
- You have had more than two infections of thrush in the last six months
- You or your partner have ever had a sexually transmitted disease
- You are aged under 12 or over 60
- You have ever had an allergic reaction to Canesten or any other vaginal antifungal products
- You have any of the following symptoms:
 - Irregular vaginal bleeding
 - Abnormal vaginal bleeding or a blood-stained discharge
 - Ulcers, blisters or sores of the vagina or vulva
 - Lower abdominal pain
 - Back pain
 - Shoulder pain
 - Pain or difficulty in passing urine
 - Fever or chills
 - Feeling sick or vomiting
 - Diarrhoea

- A foul smelling discharge from the vagina

This is because Canesten Combi Pessary & Cream may not be the right treatment for you.

Taking other medicines

If you are taking tacrolimus or sirolimus (immunosuppressant medicine), then you should tell your doctor, because he or she will monitor the levels of this medicine in your blood.

Important information about some of the ingredients:

The cream contains cetostearyl alcohol which may cause local skin irritation (e.g. rash, itching or redness). This product contains 20 mg/g benzyl alcohol. Benzyl alcohol may cause allergic reactions. Benzyl alcohol may cause mild local irritation.

Special precautions:

Sexual intercourse should be avoided while using this product. 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, spermicides or other vaginal products while using this product.

Pregnancy and breast-feeding:

Avoid using this medicine during the first trimester of pregnancy. If you are pregnant, breast-feeding or trying for a baby, tell your doctor or midwife before using Canesten Combi Pessary & Cream. Use of the applicator is not advised during pregnancy. Breast-feeding should be discontinued during treatment with this medicine.

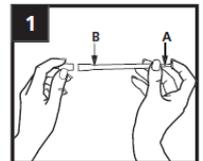
3. How to use Canesten Combi

The Pessary:

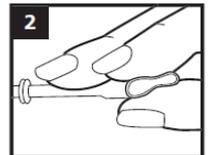
The applicator should be used to insert the pessary as high as possible into the vagina, preferably before going to sleep at night for convenient and comfortable treatment.

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

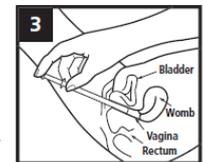
1. Remove the applicator from the packaging. Pull out the plunger A until it stops. Remove the pessary from the foil blister pack and place firmly into the applicator B (image 1).



2. To fit the pessary into the applicator, the holder of the applicator needs to be squeezed lightly at both sides. The pessary fits tightly into the applicator and needs to be squeezed into the holder to about 1cm (image 2).



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 (image 3).



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 because it is quite common to notice a white chalky residue after using the pessary. This does not mean that the treatment has not worked. However, if you notice pieces of undissolved pessary, speak to your doctor or a pharmacist, as the treatment may not have worked properly.

The Cream:

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

Women:

To treat the itching and soreness of the vulva (vulvitis), 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.

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.

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 two months you should see your doctor.

The 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. Avoid contact with the eyes.

4. Possible Side Effects

Like all medicines, Canesten Combi Pessary & 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

Rarely, immediately after you insert the pessary or apply the cream you might experience:

- Mild burning or irritation

Other potential side effects that have been reported: Discomfort of the vagina or vulva, redness, swelling, burning, bleeding, peeling skin in the genital area, irritation, itching, pain in the lower stomach region, low blood pressure.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

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

5. How to store Canesten Combi

Keep out of the sight and reach of children.

This product should be stored in the original carton. Do not store above 25 °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. Contents of the pack and other information

What Canesten Combi Pessary & Cream contains:

Pessary:

- The active substance is clotrimazole at a strength of 500 mg.

- The other ingredients are lactose monohydrate, cellulose microcrystalline, lactic acid, maize starch, crospovidone, calcium lactate pentahydrate, magnesium stearate, silica colloidal anhydrous and hypromellose.

Cream:

- The active substance is clotrimazole at a strength of 2% w/w (20 mg/g).
- The other ingredients are benzyl alcohol, polysorbate 60, sorbitan stearate, cetyl palmitate, cetostearyl alcohol, octyldodecanol and purified water.

See section 2 'Important information about some of the ingredients' for benzyl alcohol and cetostearyl alcohol advice.

What Canesten Combi Pessary & Cream looks like and contents of the pack:

Canesten Combi Pessary & Cream contains a full course of treatment, which consists of a single white pessary held inside a foil blister pack, one applicator for insertion of the pessary into the vagina and one 10g tube of white external cream.

Manufacturer:

Bayer Pharma AG/Bayer AG, 51368 Leverkusen, Germany or GP Grenzach Produktions GmbH, 79639 Grenzach-Wyhlen, Germany..

Product procured from within the EU, repackaged and distributed by the PPA Holder: PCO Manufacturing Ltd., Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath, Ireland.

Parallel Product Authorisation Number: PPA 465/48/3

Canesten is a registered trademark of Bayer Intellectual Property GmbH.

Remember: If you have any doubts about using Canesten Combi Pessary & 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.

This leaflet was last revised in November 2020