

Package leaflet: Information for the user

Canesten® 500 mg Pessary

clotrimazole

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

This medicine is available without prescription. However, you still need to use Canesten 500 mg Pessary 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.
- 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.
- You must contact a doctor if your symptoms worsen or do not improve in 7 days.

WHAT IS IN THIS LEAFLET

1. What is Canesten 500 mg Pessary and what is it used for
2. What You need to know before you use Canesten 500 mg Pessary
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1. WHAT IS CANESTEN 500 mg PESSARY AND WHAT IS IT USED FOR

Canesten 500 mg Pessary is a single application for treatment of vaginal thrush. It is inserted into the vagina for the treatment at the site of infection.

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

The active substance in Canesten 500 mg Pessary 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. WHAT YOU NEED TO KNOW BEFORE YOU USE CANESTEN 500 mg PESSARY

Do not use Canesten 500 mg Pessary:

- If you are allergic (hypersensitive) to clotrimazole or any of the other ingredients of Canesten 500 mg Pessary (listed in section 6).
- During your period as it may be less effective.

Warnings and Precautions:

Talk to your doctor or pharmacist before using **Canesten® 500mg Pessary**

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 of the other ingredients (listed in section 6).
- 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.
 - Redness, irritation or swelling associated with recent use of Canesten 500mg Pessary.
 - 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 500 mg Pessary 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.

Special precautions:

Avoid sexual intercourse while using this product, as the infection could be transferred to your partner. As with other 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 breastfeeding:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine. Canesten 500mg Pessary can be used in pregnancy and breastfeeding, but only under the supervision of your doctor or midwife. You must follow his/her instructions for use.

Use of the applicator is not advised during pregnancy.

3. HOW TO USE CANESTEN 500 mg PESSARY

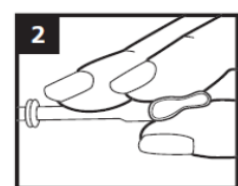
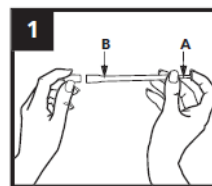
Always use this medicine exactly as described in this leaflet or as your pharmacist has told you. Check with your pharmacist if you are not sure:

If Canesten 500 mg Pessary has been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely:

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.

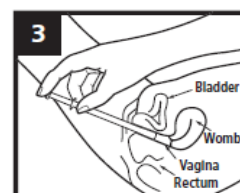
Wash your hands before removing the foil from the blister pack and again afterwards when you have used the applicator.

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).
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.

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 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.

If your vagina and vulva are itchy and sore, Canesten Cream should also be used. 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.

Canesten 500 mg Pessary is for use in the vagina only:
Do not put the pessary in your mouth or swallow it
Avoid contact with the eyes. If the pessary 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 500 mg Pessary can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the pessary. 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.
 - Low blood pressure.
- After you insert the pessary you might experience:
- Mild burning, irritation.

Other potential side effects that have been reported:

- Discomfort of the vagina or vulva, redness, swelling, bleeding, peeling skin in the genital area, itching, rash, vaginal discharge, pain (e.g. abdominal or pelvic area).

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 HPRC 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 500 mg PESSARY

Keep out of the sight and reach of children.

Do not store above 25 °C. Store in the original package.

Do not use this medicine after the expiry date which is stated on the carton and blister after ΛΗΞΗ or 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 Canesten 500 mg Pessary contains:

- The active substance is clotrimazole. Each pessary contains 500 mg clotrimazole.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, lactic acid, maize starch,

crospovidone, calcium lactate pentahydrate, magnesium stearate, colloidal anhydrous silica and hypromellose.

Product sourced from Greece also contain purified water.

What Canesten 500 mg Pessary looks like and contents of the pack:

Canesten 500 mg Pessary contains a single white pessary held inside a foil blister pack and one applicator for insertion of the pessary into the vagina.

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

Manufacturer

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

Parallel Product Authorisation Number: PPA 465/48/2

Remember: If you have any doubts about using Canesten® 500 mg Pessary 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.

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This leaflet was last revised in March 2022.