

PACKAGE LEAFLET: INFORMATION FOR THE USER

CANESTEN

500mg Pessary

CLOTRIMAZOLE

• *This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine 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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •*

What is in this leaflet?

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1. WHAT IS CANESTEN® 500mg PESSARY AND WHAT IS IT USED FOR?

Canesten 500mg Pessary is a full course of treatment for vaginal thrush (candidiasis). It is inserted into the vagina for treatment at the site of infection.

The active substance in Canesten 500mg 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. BEFORE YOU USE CANESTEN® 500mg PESSARY

Do not use Canesten® 500mg Pessary:

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

Special precautions:

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, 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 500mg Pessary. If you have informed your doctor or midwife already, follow his/her instructions carefully.

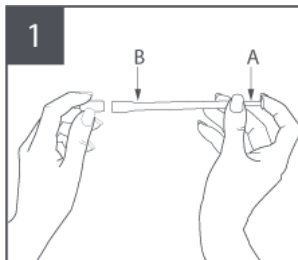
To treat internal thrush, your doctor may recommend that you use the pessary without the help of an applicator.

3. HOW TO USE CANESTEN® 500mg PESSARY

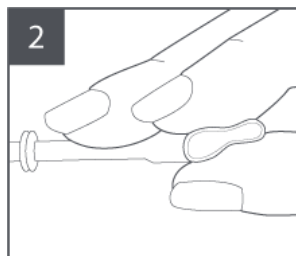
Unless directed otherwise by your doctor, the pessary should be inserted as high as possible into the vagina, preferably before going to sleep at night for convenient and comfortable treatment.

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

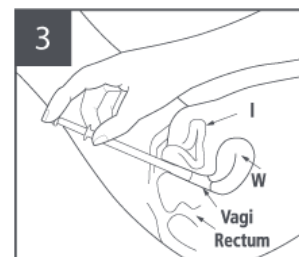
1. Remove the applicator from the packaging. Pull out the plunger A until it stops. Remove the pessary from the foil blister pack and place firmly into the applicator B.



2. 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.

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® 500mg Pessary is for use in the vagina only:

Do not put the pessary in your mouth or swallow it.

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 500mg 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.

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.

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® 500mg PESSARY

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

Do not store above 25°C.

Do not use Canesten 500mg Pessary after the expiry date which is stated at one end of the carton and on the foil blister strip of the pessary. 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® 500mg Pessary contains:

- The active substance is clotrimazole at a strength of 500mg.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, lactic acid, maize starch, crospovidone, calcium lactate pentahydrate, magnesium stearate, colloidal anhydrous silica and hypromellose.

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

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

Marketing Authorisation Holder:

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

Manufacturer:

Bayer Pharma AG, D-51368, Leverkusen, 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® 500mg 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.

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 September 2015.