

Package leaflet: Information for the user

Canesten® 500mg Soft Vaginal Capsule Clotrimazole

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

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

- 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 talk to a doctor if you do not feel better or if you feel worse after 7 days.

WHAT IS IN THIS LEAFLET

1. What Canesten Soft Vaginal Capsule is and what it is used for
2. What you need to know before you use Canesten Soft Vaginal Capsule
3. How to use Canesten Soft Vaginal Capsule
4. Possible side effects
5. How to store Canesten Soft Vaginal Capsule
6. Contents of the pack and other information

1. WHAT CANESTEN® SOFT VAGINAL CAPSULE IS AND WHAT IT IS USED FOR

Canesten Soft Vaginal Capsule is a single application for the treatment of vaginal thrush. It is inserted into the vagina for 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 Soft Vaginal Capsule 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® SOFT VAGINAL CAPSULE

Do not use Canesten® Soft Vaginal Capsule:

- If you are allergic to clotrimazole or any of the other ingredients of Canesten Soft Vaginal Capsule (*listed in Section 6*).

Warnings and precautions

Talk to your doctor or pharmacist before using Canesten® Soft Vaginal Capsule 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 16 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.
- 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 Soft Vaginal Capsule may not be the right treatment for you.

Special precautions:

As with other soft vaginal capsules, 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. Do not use this product during your period as it may be less effective.

Children

Not for use in children under 16.

Other medicines and Canesten Soft Vaginal Capsule:

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 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 Soft Vaginal Capsule 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.

Important information about some of the ingredients:

Canesten® Soft Vaginal Capsule contains soya oil. If you are allergic to peanut or soya, do not use this medicinal product.

3. HOW TO USE CANESTEN® SOFT VAGINAL CAPSULE

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

The applicator should be used to insert the soft vaginal capsule 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 soft vaginal capsule from the foil blister pack and place firmly into the applicator B.
2. Fix the Soft Vaginal Capsule firmly into the designated holder of the applicator B, by a light twist. The soft vaginal capsule 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 soft vaginal capsule 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 soft vaginal capsule dissolves in the vagina, it may be helpful to wear a panty liner.

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.

Canesten® Soft Vaginal Capsule is for use in the vagina only: Do not put the soft vaginal capsule in your mouth or swallow it.

If the soft vaginal capsule 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, this medicine can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the soft vaginal capsule. 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 Canesten soft vaginal capsule you might experience:

- Itching, rash, swelling, redness, discomfort, burning, bleeding, vaginal discharge, irritation or vaginal peeling.
- Pain (e.g. abdominal or pelvic area).
- Nausea

If you experience any of the above effects or react badly to the Soft Vaginal Capsule in any other way not listed in this leaflet, tell your doctor or pharmacist 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 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® SOFT VAGINAL CAPSULE

Keep out of the sight and reach of children.

This medicinal product does not require any special temperature storage precautions.

Do not use this medicine after the expiry date which is stated at one end of the carton and on the foil blister strip after 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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION**What Canesten® Soft Vaginal Capsule contains:**

- The active substance is clotrimazole. Each soft vaginal capsule contains 500mg clotrimazole.
- The other ingredients are white soft paraffin, liquid paraffin, gelatin, glycerol, titanium dioxide (E171), quinoline yellow (E104), sunset yellow (E110), lecithin (source of soya oil), medium-chain triglycerides.

See Section 2 'Important information about some of the ingredients' for soya oil advice.

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

Canesten Soft Vaginal Capsule contains a single yellow teardrop-shaped soft vaginal capsule held inside a foil blister pack and one applicator for insertion of the soft vaginal capsule into the vagina. Each applicator is for single use only.

Marketing Authorisation Holder:

Bayer Ltd., The Atrium, Blackthorn Road, Dublin 18.

Manufacturer:

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

Remember: If you have any doubts about using Canesten® Soft Vaginal Capsule 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 XX 2021.

Canesten is a registered trademark of Bayer AG, Germany.