

Canesten® Duopak
clotrimazole

Read all of this leaflet carefully before you start using this medicine because it contains important information for you. Always use this medicine exactly as described in this leaflet or as your pharmacist has 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 contact a doctor if your symptoms worsen or do not improve in 7 days.

WHAT IS IN THIS LEAFLET

1. What is Canesten Duopak and what is it used for?
2. What you need to know before you use Canesten Duopak
3. How to use Canesten Duopak
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6. Contents of the pack and other information

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

Canesten Duopak 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 Duopak 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. WHAT YOU NEED TO KNOW BEFORE YOU USE CANESTEN® DUOPAK

Do not use Canesten® Duopak:

- If you are allergic (hypersensitive) to clotrimazole or any of the other ingredients, including cetostearyl alcohol or benzyl alcohol, of Canesten Duopak (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® Duopak 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 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 Duopak.
 - Lower abdominal pain.
 - Shoulder pain.
 - Back 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 Duopak may not be the right treatment for you.

Other medicines and Canesten Duopak:

Tell your pharmacist if you are using, have recently used or might use any 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 20mg/g benzyl alcohol in each gram of cream. 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 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 Duopak 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® DUOPAK

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:

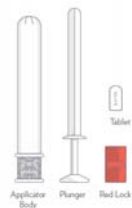
The Pessary:

If Canesten Duopak 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 on **six consecutive nights** for convenient and comfortable treatment. Alternatively, two pessaries may be inserted into the vagina before going to sleep on three consecutive nights.

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

1. Remove the applicator from the packaging and pull out the plunger and red lock from the applicator body.



2. Remove the pessary from the foil blister pack and place into the open end of the applicator body with the curved edge of the pessary facing down. Push the plunger and lock into the applicator body until you feel a click.



3. Once you have felt the click, remove the lock from the plunger and then carefully insert the applicator as deep as is comfortable into the vagina (this is easiest when lying on your back with your knees bent up) up to the patterned grip zone, without pressing on the plunger.



4. Hold the applicator body at the patterned grip zone and slowly push the plunger all the way until it stops, so that the pessary is deposited into the vagina.



5. Remove the applicator. After use, disassemble all the components for cleaning and wash thoroughly in warm (not boiling) soapy water, rinse for 30 seconds and wipe the parts carefully. Store it in a clean and safe place.



For re-use, ensure the red lock is replaced on the plunger and repeat the process from step 2. After completing the treatment, dispose of the applicator and red lock 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 Duopak 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.
- Low blood pressure.

After you insert the pessary or apply the cream 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® DUOPAK

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

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 pessaries and on the end of the tube of cream. 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 dispose of medicines you no longer use. These measures will help to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Canesten® Duopak contains:

Pessary:

- The active substance is clotrimazole at a strength of 100mg.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, lactic acid, maize starch, crospovidone, calcium lactate pentahydrate, magnesium stearate, colloidal anhydrous silica and hypromellose.

Cream:

- The active substance is clotrimazole at a strength of 1% w/w (10mg/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® Duopak looks like and contents of the pack:

Canesten Duopak contains a full course of treatment, which consists of six 100mg pessaries held inside a foil blister pack, one applicator for insertion of the pessary into the vagina and one 20g tube of white external cream.

The Canesten 100mg Pessaries and 1% cream are also available separately. The pessaries come in a box of six and the cream comes in tubes of 20g and 50g.

Marketing Authorisation Holder:

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

Manufacturer:

GP Grenzach Produktions GmbH, Germany

Remember: If you have any doubts about using Canesten® Duopak 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 approved in XXXX 2022.

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