

Patient Leaflet – Information for the user

Canesten Internal Cream Clotrimazole 10% w/w

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 doctor, pharmacist or nurse have told you.

This medicine is available without prescription. However, you still need to use Canesten Internal 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.
- 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 seven days.

WHAT IS IN THIS LEAFLET

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1. WHAT IS CANESTEN® INTERNAL CREAM AND WHAT IS IT USED FOR?

Canesten Internal Cream is a single application, full course treatment for vaginal thrush. It is a soothing intravaginal cream in a prefilled applicator for treatment at the site of infection. Canesten Thrush Cream is used to treat adults and children aged 12 years and over.

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

The active substance in Canesten Internal 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.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE CANESTEN® INTERNAL CREAM

Do not use Canesten® Internal Cream:

- If you are allergic (hypersensitive) to clotrimazole or any of the other ingredients including cetostearyl alcohol or benzyl alcohol, of Canesten Internal Cream (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 Internal Cream 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 two months.
- You or your partner have ever had a sexually transmitted disease.
- You are aged under 12 or over 60.
- You are or may be pregnant.
- 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 Internal 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:

This product contains cetostearyl alcohol which may cause local skin irritation (e.g. rash, itching or redness). This product contains 10 mg/g benzyl alcohol. Benzyl alcohol may cause allergic reactions. Benzyl alcohol may cause mild local irritation.

Special precautions:

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

As use of the applicator is not advised during pregnancy, to treat internal thrush, your doctor or midwife may recommend that you use a treatment that can be inserted into the vagina without the use of an applicator, such as a clotrimazole pessary.

3. HOW TO USE CANESTEN® INTERNAL CREAM

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 cream 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. Keeping the red cap in place, insert the tip of plunger A into the applicator B (approximately 1cm).

(Image 1)

2. Twist and pull to remove the red cap C. Be careful not to press the plunger in any further before you have inserted the applicator into the vagina. This will avoid wasting any cream.

(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 pre-measured dose of cream 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.

The cream is deposited in the vagina, but it is quite common to notice a slight discharge after using the cream and therefore it may be helpful to wear a panty liner. This does not mean that the treatment has not worked.

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® Internal Cream is for use in the vagina only:

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

If the cream is 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 Internal Cream can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the 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 apply Canesten Vaginal Cream you might experience:

- Discomfort of the vagina or vulva, redness, swelling, burning, bleeding, peeling skin in the genital area, irritation, 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 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® INTERNAL CREAM

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

Do not store above 25°C.

Do not use Canesten Internal Cream after the expiry date which is stated at one end of the carton, on the applicator and on the applicator foil wrapping. 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® Internal Cream contains:

- The active substance is clotrimazole at a strength of 500mg (10% w/w).
- The other ingredients are benzyl alcohol, polysorbate 60, sorbitan stearate, cetostearyl alcohol, isopropyl myristate, cetyl palmitate and water.

See *Section 2* 'Important information about some of the ingredients' in relation to cetostearyl alcohol and benzyl alcohol.

What Canesten® Internal Cream looks like and contents of the pack:

Canesten Internal Cream is available in single-dose packs containing 5g of white cream in a pre-filled applicator.

Marketing Authorisation Holder:

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

Manufacturer:

Kern Pharma S.L.

Poligon Industrial Colon II, Calle Venus 72

08228 Terrassa, Barcelona, Spain.

Remember: If you have any doubts about using Canesten® Internal 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 approved in xxx 2021

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