

PATIENT INFORMATION LEAFLET

Canesten® Thrush Cream (clotrimazole)

Read all of this leaflet carefully because it contains important information for you. This medicine is available without prescription. However, you still need to use Canesten Thrush 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.
- You must contact a doctor if your symptoms worsen or do not improve in 7 days.
- If you have any unusual effects after using this product, tell your doctor or pharmacist.

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1. WHAT IS CANESTEN THRUSH CREAM AND WHAT IS IT USED FOR?

Canesten Thrush Cream relieves irritation of the vulva (vulvitis) which is caused by vaginal thrush (candidiasis). Although this cream provides relief from the external irritation caused by vaginal thrush, it cannot treat any internal (vaginal) cause of the infection. Ask your doctor or pharmacist to recommend a treatment for this.

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

The active substance in Canesten Thrush 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. BEFORE YOU USE CANESTEN THRUSH CREAM

Do not use Canesten Thrush Cream:

- If you are allergic (hypersensitive) to clotrimazole or any of the other ingredients of Canesten Thrush Cream (see Section 6. Further Information and contents of the pack)

Before using Canesten Thrush Cream, you should see your doctor 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 vaginal antifungal products.
- 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.
 - Redness, irritation or swelling associated with recent use of Canesten Thrush Cream.
 - Shoulder pain.
 - Pain or difficulty in passing urine.
 - Fever or chills.
 - Diarrhoea.
 - A foul smelling discharge from the vagina.

This is because Canesten Thrush Cream may not be the right treatment for you.

Important information about some of the ingredients:

This product contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

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:

Avoid using this medicine during the first trimester of pregnancy. If you are pregnant or trying for a baby, tell your doctor or midwife before using Canesten Thrush Cream. Breast-feeding should be discontinued during treatment with this medicine.

3. HOW TO USE CANESTEN THRUSH CREAM

Women:

If Canesten Thrush Cream 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:

- Before use, pierce the tube seal by inverting the cap over the end of the tube and press.
- 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. A product to treat the internal (vaginal) infection should be used at the same time.

Treatment should be continued until symptoms of the infections disappear. Consult your doctor if the symptoms of your infection do not improve within seven days of finishing treatment for the internal infection.

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.

Canesten Thrush Cream is for external use 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 Thrush 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.

Rarely, immediately after you apply the cream you might experience:

- Mild burning or irritation.

If this is intolerable, stop treatment and see your doctor as soon as possible.

Very rarely, Canesten Thrush Cream may cause side effects which can be very similar to the symptoms of the infection. If any of these symptoms gets worse, stop treatment and see your doctor as soon as possible. These symptoms may include:

- Burning, pain or itching.
- Redness.
- Rash.
- Swelling.

Other potential side effects that have been reported: Peeling skin, blisters, low blood pressure.

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, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971 Fax: +353 1 6762517
Website: www.hpra.ie E-mail: medsafety@hpra.ie

By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE CANESTEN THRUSH CREAM

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

This product should be stored in the original carton. This medicine does not require any special storage conditions. Do not use this medicine after the expiry date (Exp) which is stated at one end of the carton and on the end of the tube of cream. This 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 any medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Canesten Thrush Cream contains:

The active substance is clotrimazole. Each gram of cream contains 20mg clotrimazole (2% w/w).

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 cetostearyl alcohol advice.

What Canesten Thrush Cream looks like and contents of the pack:

Canesten Thrush Cream is available in tubes containing 20g vaginal cream.

Manufacturer:

Manufactured by: Kern Pharma S.L.,
Poligono Industrial Colon II, C/Venus 72, 08228 Terrassa
Barcelona, Spain.

Procured from within the EU and repackaged by:
Doncaster Pharmaceuticals Group Ltd, Kirk Sandall,
Doncaster, DN3 1QR, UK.
PPA holder: Imbat Ltd., Unit L2, North Ring Business Park,
Santry, Dublin 9.
Distributed by: Eurodrug Ltd., Unit L2, North Ring Business
Park, Santry, Dublin 9.

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Remember: If you have any doubts about using Canesten Thrush 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.

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