

Canesten®

Thrush Combi Soft Gel Pessary & External Cream

500mg vaginal capsule & 2% w/w 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 Combi Soft Gel Pessary and External 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 COMBI AND WHAT IS IT USED FOR?

Canesten Thrush Combi Soft Gel Pessary and External Cream 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 Thrush Combi 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 COMBI

Do not use Canesten® Thrush Combi Soft Gel Pessary and External Cream:

- If you are allergic (hypersensitive) to clotrimazole or any of the other ingredients, including cetostearyl alcohol, of Canesten Thrush Combi Soft Gel Pessary and External Cream (see Section 6. Further Information).
- To treat nail and scalp infections.

Before using Canesten® Thrush Combi Soft Gel Pessary and External 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 16 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.
 - 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 Thrush Combi may not be the right treatment for you.

Important information about some of the ingredients:

The cream contains cetostearyl alcohol which may cause local skin irritation (e.g. rash, itching or redness).

Special precautions:

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, 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.

Do not use this product during your period as it may be less effective.

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 Thrush Combi. 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® THRUSH COMBI

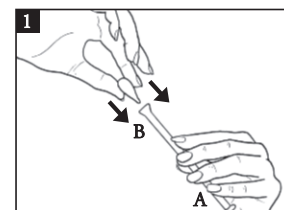
If Canesten Thrush Combi has been prescribed for you by your doctor, follow any instructions he/she may have given you. If you purchased this product without a prescription, follow these directions closely.

The Soft Gel Pessary:

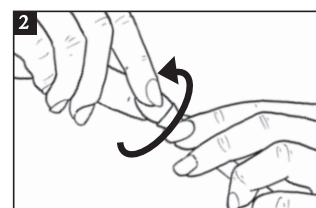
The applicator should be used to insert the pessary as high as possible into the vagina, preferably before going to sleep at night for convenient and comfortable treatment.

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

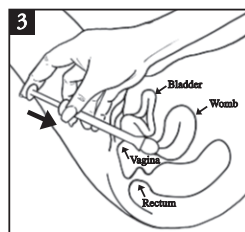
1. Remove the applicator from the packaging. Pull out the plunger A until it stops. Remove the pessary from the foil blister pack and place firmly into the applicator B.



2. Fix the Soft Gel Pessary firmly into the designated holder of the applicator B, by a light twist. The pessary fits tightly into the applicator.



- 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.



- 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.

The Cream:

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. Treatment should be continued until the symptoms of the infection disappear.

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.

The Soft Gel 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Canesten Thrush Combi Soft Gel Pessary and External Cream 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.

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.

After you apply the cream you might experience:

- Itching, rash, blisters, burning, discomfort, swelling, redness, irritation or peeling of skin.

If you experience any of the above effects, 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 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® THRUSH COMBI

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

Do not store above 30°C.

This product should be stored in the original carton in a dry place in order to protect from moisture.

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 pessary and on the end of the tube of cream. 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® Thrush Combi Soft Gel Pessary and Cream contains: Soft Gel Pessary:

- The active substance is clotrimazole at a strength of 500mg.
- The other ingredients are white soft paraffin, liquid paraffin, gelatin, glycerol, water, titanium dioxide (E171), quinolone yellow (E104), sunset yellow (E110), lecithin, medium-chain triglycerides.

Cream:

- The active substance is clotrimazole at a strength of 2% w/w.
- The other ingredients are benzyl alcohol, polysorbate 60, sorbitan stearate, cetyl palmitate, cetostearyl alcohol, octyldodecanol and purified water.

See Section 2 'Do not use' and 'Important information about some of the ingredients' for cetostearyl alcohol advice.

What Canesten® Thrush Combi Soft Gel Pessary and External Cream looks like and contents of the pack:

Canesten Thrush Combi Soft Gel Pessary and External Cream contains a full course of treatment, which consists of a single yellow teardropshaped soft vaginal capsule held inside a foil blister pack, one applicator for insertion of the pessary into the vagina and one 10g tube of white external cream.

Marketing Authorisation Holder:

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

Manufacturer:

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

Remember: If you have any doubts about using Canesten® Thrush Combi Soft Gel Pessary and External 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.

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 June 2014.

Bayer

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Due to regulatory changes, the content of the following Patient Information Leaflet may vary from the one found in your medicine pack. Please compare the 'Leaflet prepared/revised date' towards the end of the leaflet to establish if there have been any changes.

If you have any doubts or queries about your medication, please contact your doctor or pharmacist.

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