

Canesten®

Internal Cream

Clotrimazole 10% w/w

PATIENT INFORMATION LEAFLET
PLEASE READ THIS LEAFLET CAREFULLY BEFORE USING CANESTEN® INTERNAL CREAM.

Thrush is a common infection that most women have at some time in their lives and is not caused by a lack of personal hygiene.

Thrush is caused by a yeast (fungus) called candida which may live harmlessly in the vagina 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 level of yeast increases, it 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.

If this is the first time you have had these symptoms, talk to your doctor before using any treatment.

What does Canesten® Internal Cream contain?

It is a white cream for use inside the vagina. It contains 10% w/w of the active ingredient clotrimazole. Other ingredients are benzyl alcohol, polysorbate 60, sorbitan stearate, cetostearyl alcohol, isopropyl myristate, cetyl palmitate and water.

The single-dose 5g pack is a full course of treatment.

Clotrimazole is an antifungal agent which fights the cause of infections such as thrush.

Marketing Authorisation Holder: Bayer plc,
Consumer Care Division, Bayer House, Strawberry Hill,
Newbury, Berkshire, RG14 1JA. United Kingdom.

Manufacturer: Kern Pharma S.L., Terrassa, Spain.

What is Canesten® Internal Cream?

Canesten Internal Cream is a single application for the treatment of vaginal thrush.

It is a soothing intravaginal cream in a prefilled applicator for treatment at the site of infection.

When not to use Canesten® Internal Cream

Do not use this product if you have previously had an allergic reaction to the active ingredient, clotrimazole or any of the other ingredients in this product. If you are unsure about this, ask your doctor.

See your doctor as soon as possible and do not use Canesten Internal Cream if 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 Internal Cream may not be the right treatment for you.

If you are unsure whether you have thrush, check with your doctor before using this product.

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

What special precautions should be taken?

If you are pregnant or are trying for a baby, tell your doctor or midwife before using Canesten Internal Cream. If you have informed your doctor or midwife already, follow his/her instructions carefully. During pregnancy, extra care should be taken when inserting the applicator.

Before using this product, you should see your doctor if:

- you have had more than two infections of vaginal 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 years
- you have ever had an allergic reaction to Canesten or any other vaginal antifungal products.

As with other creams and pessaries, this product may reduce the effectiveness of rubber contraceptives, such as condoms and diaphragms, when used together. Consequently, you should use alternative precautions for at least five days after using this product.

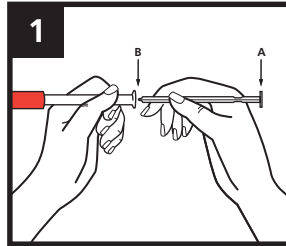
This product contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

When and how to use Canesten® Internal Cream.

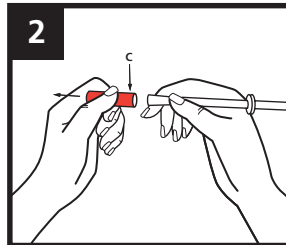
The single dose treatment of cream is in a prefilled applicator in a foil blister pack.

The cream should be inserted high into the vagina, preferably at night so that it can work whilst you sleep.

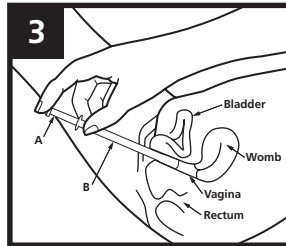
Remove the applicator from the foil packaging. Keeping the red cap in place, insert the tip of plunger A into the applicator B (approximately 1cm).



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.



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. 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 six months you should see your doctor.

Canesten Internal Cream should be used in the vagina only. Do not put it in your mouth or swallow it. If you do accidentally swallow it, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

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 hard with sponges or flannels and avoid hot baths with strong perfumed oils

If you are still worried or have any further questions about the symptoms or the treatment of thrush, do not hesitate to ask your doctor or pharmacist.

What side effects may I experience?

Rarely, you may experience mild burning or irritation immediately after you apply the cream. Canesten Internal Cream may also cause side effects which can be very similar to the symptoms of thrush. If the redness, burning, pain, itching or swelling get worse, see your doctor as soon as possible.

As with all medicines, some people may be allergic to the cream. If you are allergic, a reaction will occur soon after you start using it. You may have a local reaction similar to those described above, or very rarely a generalised allergic reaction which may appear as rash, nausea, faintness, facial swelling, low blood pressure, diarrhoea and shortness of breath.

If you experience any of these effects, tell your doctor immediately.

If you feel you are reacting badly to this medicine in any other way, discuss this with your doctor or pharmacist.

Important:

Do not store above 25°C.

Keep out of the reach and sight of children.

Do not use Canesten Internal Cream after the expiry date (this will be printed at one end of the carton, on the applicator and the applicator foil wrapping.)

Date of preparation of leaflet: November 2005.

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Internal Cream
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REMEMBER: If you have any doubts about using Canesten Internal Cream correctly, seek the advice of your pharmacist.

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.

Bayer



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