

Canesten

COMBI

Patient Information Leaflet

Thrush is a common infection that most women have 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 pH balance of the vagina 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 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® COMBI CONTAIN?

The pessary contains 500mg of the active ingredient Clotrimazole Ph.Eur. Other ingredients are lactose, microcrystalline cellulose, lactic acid, maize starch, povidone, calcium lactate, magnesium stearate, silicon dioxide and poly (O-hydroxypropyl-O-methyl) cellulose.

The 10g tube of cream contains 2% w/w Clotrimazole Ph.Eur. Other ingredients are benzyl alcohol, Polysorbate 60, sorbitan monostearate, cetyl esters wax, cetyl stearyl alcohol, 2-octyldodecanol and purified water.

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

WHAT IS CANESTEN® COMBI?

Canesten Combi is a complete thrush treatment because it contains:

- a soothing cream to start relieving the itch immediately
- a pessary for insertion into the vagina for treatment at the site of infection. The pessary also contains an ingredient that helps restore the vagina's pH balance.

WHEN NOT TO USE CANESTEN® COMBI

Do not use the pessary or cream if you have previously had an allergic reaction to the active ingredient, clotrimazole. If you are unsure about this, ask your doctor.

See your doctor as soon as possible and do not use the pessary 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 Combi may not be the right treatment for you.

If you are unsure whether you have thrush, check with your doctor before using Canesten Combi.

WHAT SPECIAL PRECAUTIONS SHOULD BE TAKEN?

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

Before using the pessary, you should see your doctor if:

- 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 years
- you have ever had an allergic reaction to Canesten or any other vaginal antifungal products.

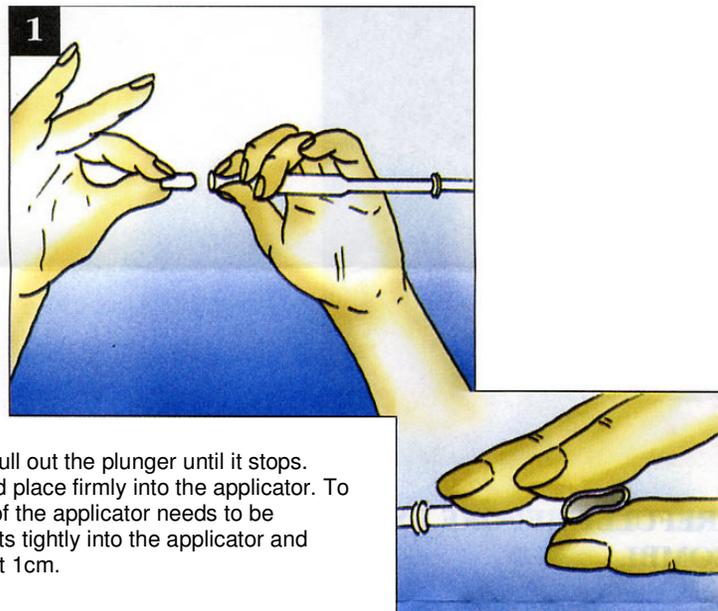
As with other creams and pessaries, this product may reduce the effectiveness of rubber contraceptives, such as condoms or diaphragms, when used together. Consequently, you should use alternative precautions for at least five days after using this product.

WHEN AND HOW TO USE CANESTEN® COMBI

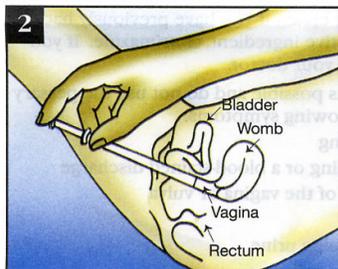
The full course of treatment consists of a Canesten Pessary held inside a foil blister pack, an applicator for insertion of the pessary into the vagina and a tube of Canesten Thrush Cream.

THE PESSARY

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



Remove the applicator from the packaging. Pull out the plunger until it stops. Remove the pessary from the blister pack and place firmly into the applicator. To fit the pessary into the applicator, the holder of the applicator needs to be squeezed lightly at either side. The pessary fits tightly into the applicator and needs to be squeezed into the holder to about 1cm.



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 because it is quite common to notice a slight white residue (chalky) after using the pessary. This does not mean that the treatment, has not worked.

THE CREAM

For the treatment of the itching and soreness (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.

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 as well, even if they have no symptoms of thrush.

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.

The symptoms of thrush should disappear within three days of treatment. If no improvement is seen after seven days, tell your doctor.

The Canesten Pessary should be used in the vagina only. Your Canesten Thrush 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.

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, the pessary or cream may cause side effects in some people. The side effects are very similar to the symptoms of thrush. If the redness, burning, irritation or swelling get worse, see your doctor as soon as possible.

As with all medicines, some people may be allergic to the pessary or cream. If you are allergic to the pessary or cream a reaction will occur soon after you start using them. An allergic reaction may appear as a rash, itching, nausea, faintness or facial swelling. If you experience any of these effects, tell your doctor immediately.

If you feel you are reacting badly to the pessary or cream in any other way, discuss this with your doctor.

Important:

Canesten Combi should be stored in the original carton below 25°C.

Keep out of the reach and sight of children.

Do not use the pessary or cream after their expiry date (this will be printed at one end of the carton, on the end of the tube of cream and the foil blister strip of the pessary).

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If you have any questions or would like more information, call our Canesten Health Advice line on 0845 758 5030. Calls charged at local rate.

if you are calling from outside the UK please dial 00 44 845 758 5030, please note that calls will be charged at national rate.

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