

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.



Canesten®

Oral & Cream Duo®



Oral capsule: Fluconazole 150mg Thrush cream: Clotrimazole 2% w/w

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 Oral & Cream Duo 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® DUO® AND WHAT IS IT USED FOR?

Canesten Oral & Cream Duo is a complete and convenient treatment for vaginal or penile thrush.

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

The active substances in the capsule and cream are fluconazole and clotrimazole, respectively. Fluconazole and clotrimazole belong to a group of medicines called azoles and are antifungal agents which fight the cause of infections such as thrush.

2. BEFORE YOU USE CANESTEN® DUO®

Do not use Canesten® Oral & Cream Duo®:

- If you are allergic (hypersensitive) to fluconazole, clotrimazole or any of the other ingredients, including cetostearyl alcohol, of Canesten Oral & Cream Duo (see Section 6. Further Information).
- If you are taking the antihistamine terfenadine or the medicine cisapride.

Women:

If you have any of the following symptoms do not use Canesten Oral & Cream Duo and see your doctor as soon as possible:

- 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 Oral & Cream Duo may not be the right treatment for you.

Men:

Do not use Canesten Oral & Cream Duo without talking to your doctor first if:

- Your sexual partner does not have thrush.
- You have sores, ulcers or blisters on your penis.
- You have an abnormal discharge from your penis.
- Your penis has started to smell.
- You have pain or difficulty in passing urine.

This is because Canesten Oral & Cream Duo may not be the right treatment for you.

Before using Canesten® Oral & Cream Duo®, 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 fluconazole, clotrimazole or any other vaginal antifungal products.
- You have had any disease or illness affecting the liver or kidneys, or have had any unexplained jaundice.
- You suffer from any other chronic disease or illness.

Important information about some of the ingredients:

The capsule contains lactose monohydrate, so if you have been told by your doctor that you have an intolerance to some sugars contact your doctor before taking this medicinal product.

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

Special precautions:

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.

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.

Do not use Canesten Oral & Cream Duo if you are taking the antihistamine terfenadine or the medicine cisapride.

Inform your doctor if you are taking: Anticoagulants (to prevent blood clots), Sulphonylureas (to control diabetes), Hydrochlorothiazide (used to treat fluid retention and high blood pressure), Benzodiazepines (used as tranquillisers), Phenytoin (used to control epilepsy), Rifampicin or Rifabutin (antibiotics), Cyclosporin or Tacrolimus (used to reduce the immune response), Theophylline (used to control asthma), Zidovudine (used to treat HIV infection), Astemizole (antihistamine).

Taking Canesten® Oral & Cream Duo® with food and drink:

The oral capsule should be swallowed whole with a glass of water. It can be taken with or without food.

There is no known interaction with alcohol or nicotine.

Pregnancy and breast-feeding:

Do not use Canesten Oral & Cream Duo if you are pregnant, trying for a baby or breast-feeding.

3. HOW TO USE CANESTEN® DUO®

If Canesten Oral & Cream Duo 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 capsule is to treat thrush at the site of infection and should be swallowed whole with a glass of water (with or without food).

The cream is to treat the itching and soreness of the vulva (vulvitis).

- Before use, pierce the tube seal by inverting the cap over the end of the tube and press.
- 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. It should be used until symptoms of the infections disappear.

The symptoms of thrush should disappear within two days of treatment. If no improvement is seen after seven days, you must tell your doctor. If the infection returns after seven days another capsule may be taken but if you have more than two infections within six months you should see your doctor.

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 re-infection, 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 for up to two weeks.

The 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.

If you take more Canesten® Oral & Cream Duo® than you should:

If more than one capsule is taken, tell your doctor straight away or contact the Accident and Emergency Department of your nearest hospital.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Canesten Oral & Cream Duo can cause side effects, although not everybody gets them.

As with all medicines, some people may be allergic to the capsule or the cream. If you are allergic, a reaction will occur soon after you have taken or 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.

For the capsule, the most common side effects include:

- Sickness or stomach discomfort.
- Diarrhoea and wind.

Rarely, people have experienced:

- Headaches.
- Liver disorders.

The following have been reported rarely by some patients, but may not be due to the medicine:

- Skin disorders and unexpected bruising.
- Seizures.
- Hair loss.
- Recurrent infections (e.g. cold and flu).

After you apply the cream you might experience:

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

If you experience any of the above effects or react badly to the capsule or cream in any other way not listed in this leaflet, tell your doctor or pharmacist immediately.

5. HOW TO STORE CANESTEN® DUO®

Keep out of the reach and sight of children.

This product should be stored in the original carton.

Do not store above 25°C.

Do not use Canesten Oral & Cream Duo after the expiry date which is stated at one end of the carton, on the blister pack 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® Oral & Cream Duo® contains:

The oral capsule:

- The active substance is fluconazole at a strength of 150mg.
- The other ingredients are colloidal silicon dioxide, lactose monohydrate, magnesium stearate, maize starch and sodium lauryl sulphate. The capsule shell contains brilliant blue FCF (E133), titanium dioxide (E171) and gelatine. The printing ink contains shellac, black iron oxide (E172) and propylene glycol.

See Section 2 'Important information about some of the ingredients' for lactose monohydrate advice.

The 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® Oral & Cream Duo® looks like and contents of the pack:

Canesten Oral & Cream Duo contains:

- A single light blue capsule to be taken orally.
- A tube containing 10g of white external cream (Canesten® Thrush Cream).

Marketing Authorisation Holder:

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

Manufacturer:

Wasdell Packaging Ltd.,
Upper Mills Estate, Bristol Road
Stonehouse, Gloucestershire, GL10 2BJ, UK.

Remember: If you have any doubts about using Canesten® Oral & Cream Duo® correctly, seek the advice of your doctor or pharmacist.

Further information about 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.

In men, Candida can also cause thrush - a condition called balanitis (inflammation of the end of the penis). It causes any of the following symptoms: soreness and redness of the penis, tightness of the foreskin and a white, odourless discharge from the penis.

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 approved in December 2009.

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Bayer