

Canesten®

Thrush Duo®
Oral Capsule &
External Cream
150mg capsule &
2% w/w cream



Fluconazole & 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 Duo Oral & 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.

IN THIS LEAFLET

1. What is Canesten Thrush Duo and what is it used for?
2. Before you use Canesten Thrush Duo
3. How to use Canesten Thrush Duo
4. Possible side effects
5. How to store Canesten Thrush Duo
6. Further information

1. WHAT IS CANESTEN® THRUSH DUO® AND WHAT IS IT USED FOR?

Canesten Thrush 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® THRUSH DUO®

Do not use Canesten® Thrush Duo®:

- If you are allergic (hypersensitive) to fluconazole, clotrimazole, to other medicines you have taken to treat fungal infections or to any of the other ingredients, including lactose monohydrate, cetostearyl alcohol or benzyl alcohol, of Canesten Thrush Duo (see Section 6. Further Information).
- If you are taking astemizole or terfenadine (antihistamine medicines for allergies), cisapride (used for stomach upsets), pimozone (used for treating mental problems), quinidine (used for treating heart arrhythmia), erythromycin (an antibiotic for treating infections).

Women:

If you have any of the following symptoms do not use Canesten Thrush 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 Thrush Duo may not be the right treatment for you.

Men:

Do not use Canesten Thrush 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 Thrush Duo may not be the right treatment for you.

Before using Canesten® Thrush 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 ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking Canesten Thrush Duo.

Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with Canesten Thrush Duo treatment. Stop using Canesten Thrush Duo and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.

- You have had any disease or illness affecting the liver or kidneys, or have had any unexplained jaundice.
- You have heart problems, including heart rhythm problems.
- You suffer from any other chronic disease or illness.
- The fungal infection does not improve, as alternative antifungal therapy may be needed.

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 reactions (e.g. contact dermatitis). It also contains 20mg benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation.

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 Thrush Duo if you are taking astemizole, terfenadine, cisapride, pimozone, quinidine or erythromycin.

Inform your doctor if you are taking: Anticoagulants (to prevent blood clots), Sulphonylureas (to control diabetes), Hydrochlorothiazide (to treat fluid retention and high blood pressure), Benzodiazepines (tranquilisers), Phenytoin or Carbamazepine (to control epilepsy), Rifampicin or Rifabutin (antibiotics), Ciclosporin, Sirolimus, Tacrolimus or Tofacitinib

(to reduce the immune response), Theophylline (to control asthma), Zidovudine or Saquinavir (to treat HIV infection), Losartan (to reduce blood pressure), Alfentanil, Fentanyl or Methadone (to treat pain), Halofantrine (for treating malaria), Amiodarone (to control irregular heartbeats, 'arrhythmias'), Amitriptyline or Nortriptyline (anti-depressants), Ivacaftor (for treating cystic fibrosis), Statins like Simvastatin, Atorvastatin or Fluvastatin (for reducing high cholesterol levels), Non-steroidal Anti-inflammatory Drugs like Ibuprofen, Celecoxib, Diclofenac, Meloxicam or Naproxen, Olaparib (to treat ovarian cancer), Ibrutinib (used for treating blood cancer), Tolvaptan (used for treating low levels of sodium in your blood).

Taking Canesten® Thrush 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 breastfeeding:

You should not take Canesten Thrush Duo if you are pregnant, think you may be pregnant, are trying to become pregnant or breastfeeding, unless your doctor has told you so.

Fluconazole taken during the first trimester of pregnancy may increase the risk of miscarriage. Fluconazole taken at low doses during the first trimester may slightly increase the risk of a baby being born with birth defects affecting the bones and/or muscles.

Driving and using machines:

Canesten Oral Capsule may cause dizziness. If dizziness occurs after taking your capsule, you should not drive or use machines.

3. HOW TO USE CANESTEN® THRUSH DUO®

If Canesten Thrush 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® Thrush 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 Thrush 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 gets 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.

Capsule

If you experience any of the following, please contact your doctor or pharmacist immediately – you may need urgent medical attention:

- Severe condition with blistering and peeling of the skin, mouth, eyes or genitals.
- Widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).
- Liver disorders with symptoms such as yellowing of the skin or eyes, dark urine or pale stools.
- Seizures
- Change in heart rhythm or rate.

Additionally, if any of the following side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Common side effects (may affect up to 1 in 10 people) are:

- headache
- stomach discomfort, diarrhoea, feeling sick, vomiting
- increases in blood tests of liver function
- rash

Uncommon side effects (may affect up to 1 in 100 people) are:

- reduction in red blood cells which can make skin pale and cause weakness or breathlessness
- decreased appetite
- inability to sleep, feeling drowsy
- fit, dizziness, sensation of spinning, tingling, pricking or numbness, changes in sense of taste
- constipation, indigestion, wind, dry mouth
- muscle pain
- wheals, blistering (hives), itching, increased sweating
- fatigue, general feeling of being unwell, fever

Rare side effects (may affect up to 1 in 1,000 people) are:

- lower than normal white blood cells that help defend against infections and red blood cells that help to stop bleeding, respectively causing recurrent infections like cold and flu and increased bleeding/blood thinning (if you cut yourself)
- red or purple discoloration of the skin which may be caused by low platelet count, other blood cell changes

- blood chemistry changes (high blood levels of cholesterol, fats)
- low blood potassium
- shaking
- hair loss

Frequency not known, but may occur (cannot be estimated from the available data):

- hypersensitivity reaction with skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia) and inflammation of internal organs (liver, lungs, heart, kidneys and large intestine) (Drug Reaction or rash with Eosinophilia and Systemic Symptoms (DRESS)).

Cream

After you apply the cream you might experience:

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

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 or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

5. HOW TO STORE CANESTEN® THRUSH DUO®

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

Do not store above 25°C.

Do not use Canesten Thrush 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® Thrush 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 and benzyl alcohol advice.

What Canesten® Thrush Duo® looks like and contents of the pack:

Canesten Thrush Duo contains:

- A single light blue capsule with 'Canesten®' printed on it in black between two black lines. To be taken orally.
- A tube containing 10g of white external cream (Canesten® Thrush External Cream).

Marketing Authorisation Holder:

Bayer plc, 400 South Oak Way, Reading, RG2 6AD, UK.

Manufacturer:

Wasdell Packaging Ltd., Euroway Industrial Estate, Blagrove, Swindon, Wiltshire, SN5 8YW, UK

Remember: If you have any doubts about using Canesten® Thrush 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 revised in February 2022.

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