

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 Capsule

Fluconazole 150mg



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 Capsule 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® ORAL CAPSULE AND WHAT IS IT USED FOR?

Canesten Oral Capsule is a full course of treatment for thrush.

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

The active substance in Canesten Oral Capsule is fluconazole. Fluconazole belongs to a group of medicines called azoles and is an antifungal agent which fights the cause of infections such as thrush.

2. BEFORE YOU USE CANESTEN® ORAL CAPSULE

Do not use Canesten® Oral Capsule:

- If you are allergic (hypersensitive) to fluconazole or any of the other ingredients of Canesten Oral Capsule (see Section 6. Further Information).
- If you are taking the antihistamine terfenadine, the medicine cisapride or an ergot-derivative (e.g. ergotamine used for migraine).

Women:

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

Men:

Do not use Canesten Oral Capsule 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 Capsule may not be the right treatment for you.

Before using Canesten® Oral Capsule, 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 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 have heart problems, including heart rhythm problems.
- 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 an intolerance to some sugars contact your doctor before taking this medicinal 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 Capsule if you are taking the antihistamine terfenadine, the medicine cisapride or an ergot-derivative (e.g. ergotamine used for migraine).

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 tranquilisers), Phenytoin, Carbamazepine or Phenobarbital (used to control epilepsy), Rifampicin, Rifabutin or Rifapentine (antibiotics), Ciclosporin, Sirolimus or Tacrolimus (used to reduce the immune response), Theophylline (used to control asthma), Zidovudine (used to treat HIV infection), Astemizole (antihistamine), Anti-arrhythmics (to control irregular heart beats), Losartan (to reduce blood pressure), Fentanyl or Methadone (to treat pain).

Taking Canesten® Oral Capsule with food and drink:

Canesten 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 Capsule if you are pregnant, trying for a baby or breast-feeding.

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® ORAL CAPSULE

If Canesten Oral Capsule 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 full course of treatment consists of a single Canesten Oral Capsule. 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 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.

If you take more Canesten® Oral Capsule 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 Capsule can cause side effects, although not everybody gets them.

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

The following side effects have also been reported:

- Feeling sick or being sick, stomach discomfort, change in sense of taste.
- Diarrhoea and wind.
- Headaches.
- Liver disorders with symptoms such as yellowing of the skin or eyes, dark urine or pale stools.
- Change in heart rhythm or rate.
- Abnormal ECG (electrocardiogram) heart tracing.
- High blood levels of cholesterol or fat.
- Reduction in number of blood cells and platelets
- Low levels of potassium.
- Severe condition with blistering of the skin, mouth, eyes or genitals.
- Rash, itching, hair loss.
- Seizures.
- Recurrent infections (e.g. cold and flu).

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

5. HOW TO STORE CANESTEN® ORAL CAPSULE

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 Capsule after the expiry date which is stated at one end of the carton and on the blister pack. 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 Capsule contains:

- 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.

What Canesten® Oral Capsule looks like and contents of the pack:

Each pack contains a single light blue capsule with 'Canesten' printed on it.

Marketing Authorisation Holder:

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

Manufacturer:

Accord Healthcare Limited, Sage House, Pinner Road,
Harrow, Middlesex, HA1 4HF, UK.

Remember: If you have any doubts about using Canesten® Oral Capsule 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 September 2011.

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