

		Canesten Fluconazole CMI 19 May 2009
	Consumer Medicine Information	

Canesten[®] Fluconazole Capsule

Fluconazole oral capsule 150 mg

What is in this leaflet

This leaflet answers some common questions about Canesten Fluconazole Capsule.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your pharmacist has weighed the risks of you using Canesten Fluconazole Capsule against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Canesten Fluconazole Capsule is used for

Canesten Fluconazole Capsule is used to treat a fungal infection in the vagina (vaginal thrush).

This medicine belongs to a group of medicines called azole antifungals.

Canesten Fluconazole Capsule is taken by mouth and works from the inside to prevent the growth of the fungi causing your infection.

What is vaginal thrush?

Vaginal thrush is the common name for vaginal candidiasis, an infection caused by a yeast-like fungus called *Candida*. *Candida* can multiply rapidly and cause damage to the vagina when other micro-organisms aren't present in a normal balance.

Some situations which can increase susceptibility to thrush are:

- diabetes
- obesity
- illness
- fatigue
- hormonal fluctuations (pregnancy, menstrual cycle, oral contraceptive pill, HRT)
- prolonged use of antibiotics or steroids

Thrush may cause the following symptoms:

- vaginal itching

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- vaginal burning or soreness
- a white odourless discharge from the vagina (like cottage cheese)
- pain during intercourse

The symptoms below are **not** usually signs of thrush:

- abnormal or irregular vaginal bleeding
- blood stained discharge
- vulva or vaginal sores, ulcers or blisters
- lower abdominal pain
- pain when passing urine
- fever or chills
- foul smelling and/or unusual coloured discharge

See your doctor if you experience any of the above symptoms.

Ask your doctor or pharmacist if you have any questions about whether this medicine is suitable for you.

Canesten Fluconazole Capsule is a “Pharmacist Only Medicine”. It is available without a doctor’s prescription, but your pharmacist’s advice is required.

Before you take Canesten Fluconazole Capsule

When you must not take it

Do not take Canesten Fluconazole Capsule if you have an allergy to:

- any medicine containing *fluconazole*
- any other similar antifungals such as miconazole, ketoconazole or clotrimazole
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take Canesten Fluconazole Capsule if you are taking cisapride (Prepulsid®) – a medicine used to treat stomach problems.

Combining Canesten Fluconazole Capsule with cisapride may cause serious side effects such as an abnormal heart rhythm.

Canesten Fluconazole Capsule is not recommended for children under 18 years of age unless recommended by a doctor.

Safety and effectiveness in children under 18 years of age have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

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Before you start to use it

Tell your doctor or pharmacist if you are pregnant or suspect you may be pregnant.

Canesten Fluconazole Capsule is not recommended for use by pregnant women as it may affect the developing baby.

Canesten Fluconazole Capsule is not recommended for women who may be at risk of falling pregnant unless contraception is being used.

Tell your doctor if you are breast-feeding.

Canesten Fluconazole Capsule is not recommended for use by women who are breast-feeding as it passes into breast milk and may affect the baby.

See your doctor if:

- this is your first infection
- you are under 18 years of age
- you have had 3 or more infections in the last 6 months

Tell your doctor or pharmacist if you have any other health problems, including:

- any liver problems
- any heart problems
- severe kidney problems
- if you have HIV or AIDS

Tell your doctor or pharmacist if you have previously developed a rash while taking fluconazole.

Tell your doctor or pharmacist if you are taking warfarin (Marevan[®], Coumadin[®]), as bleeding or bruising may occur.

Tell your doctor or pharmacist if you are allergic to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are diabetic.

Thrush in diabetics can mean that your blood sugar levels are not well controlled. Your doctor will be able to check this for you and advise treatment.

If you have not told your doctor about any of the above, do so before you start taking Canesten Fluconazole Capsule.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any you have bought without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Canesten Fluconazole Capsule may interfere with each other. These include:

- cisapride (Prepulsid[®]) – a medicine used to treat stomach problems. **Do not take Canesten Fluconazole Capsule if you are taking cisapride.**

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- some medicines used to treat diabetes such as tolbutamide, glibenclamide, gliclazide, pioglitazone, rosiglitazone or glibenclamide
- phenytoin (Dilantin®) – a medicine used to treat epilepsy
- hydrochlorothiazide – a medicine for high blood pressure and other heart conditions
- rifampicin (Rifadin®, Rifinah®) or rifabutin (Mycobutin®) – antibiotic medicines
- tacrolimus (Prograf®) – a medicine used to prevent organ transplant rejection or treat problems with the immune system
- zidovudine (Retrovir®) – a medicine for HIV/AIDS
- warfarin (Coumadin®, Marevan®) – a medicine to treat or prevent blood clots

These medicines may be affected by Canesten Fluconazole Capsule or may affect how well it works.

Your doctor or pharmacist will have more information on medicines to be careful with or avoid while taking Canesten Fluconazole Capsule.

How to take Canesten Fluconazole Capsule

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions below, or on the box, ask your doctor or pharmacist for help.

How to take it

The complete treatment for vaginal thrush is one 150 mg capsule – only a single dose is needed. Take only one capsule. Swallow the capsule whole with a glass of water.

The capsule can be taken with or without food.

After taking Canesten Fluconazole Capsule, symptoms of thrush usually start to get better in about one day.

When to take it

Canesten Fluconazole Capsule can be taken at any time of the day.

If you are not sure what to do, ask your doctor or pharmacist.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice or go to your nearest Accident and Emergency Centre if you think you or anyone else may have taken too much Canesten Fluconazole Capsule. Do this even if there are no signs of discomfort or poisoning. You may need medical attention.

While you are taking Canesten Fluconazole Capsule

Things you must do

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Discontinue treatment and tell your doctor or pharmacist if you develop a reaction to this product.

See your doctor if the symptoms do not improve after three days, or if they become worse.

Tell all doctors, dentists and pharmacists who are treating you that you are taking or have taken Canesten Fluconazole Capsule.

Use effective contraception to prevent pregnancy while taking Canesten Fluconazole Capsule.

Things you must not do

Do not use Canesten Fluconazole Capsule to treat any other complaints unless your doctor tells you to.

Do not give your treatment to anyone else, even if you suspect they have the same condition as you.

Things to be careful of

Canesten Fluconazole Capsule is not expected to affect your ability to drive a car or operate machinery.

Things that may help to resolve Thrush

Some self help measures suggested below may help your condition. Your doctor or pharmacist can give you more information about these measures.

- blot with toilet paper after urinating (instead of wiping back to front).
- change underwear, night attire, towels and linen daily.

Avoid where possible:

- perfumed toilet paper
- fragrant soaps and bath oils
- wearing tight or synthetic underwear
- douches or vaginal deodorants

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well or experience discomfort while you are taking Canesten Fluconazole Capsule.

This medicine helps most people with vaginal thrush but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea or feeling sick, vomiting
- headache
- stomach pain
- indigestion
- diarrhoea

The list above includes the more common side effects of fluconazole. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:-

- swelling of the face, lips or tongue which may cause difficulty swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives
- fainting, seizures or fits
- flaking of the skin
- yellowing of the skin or eyes, also called jaundice
- bleeding or bruising more easily than normal, or reddish or purplish blotches under the skin
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- fast or irregular heart beat

These side effects are usually rare but can be serious and may need urgent medical attention.

This is not a complete list of all possible side effects. Others may also occur in some people and there may be some side effects not yet known.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything on this list.

After using Canesten Fluconazole Capsule

Storage

Keep your medicine in the original pack until it is time to use it.

If you take the capsule out of its packaging it may not keep well.

Keep your capsule in a cool dry place where the temperature stays below 25°C.

Do not store your medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

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Keep the treatment where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Expiry

The expiry date is marked on the foil/blister and on the carton.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Discard the medicine out of the reach of children.

Product description

What it looks like

Canesten Fluconazole Capsule is a white opaque capsule with “FC 150” printed in black on one end and “G” on the other.

Ingredients

Canesten Fluconazole Capsule

The capsule contains 150 mg fluconazole as the active ingredient. It also contains:

- lactose
- maize (corn) starch
- sodium lauryl sulphate
- colloidal hydrated silica
- magnesium stearate
- titanium dioxide
- gelatin

The ingredients in the black printing ink used for coding the capsules include:-

- shellac
- dehydrated alcohol
- isopropyl alcohol
- butyl alcohol
- propylene glycol
- ammonia solution
- potassium hydroxide
- black iron oxide

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

Manufacturer

Canesten Fluconazole Capsules are made in Canada.

Canesten Fluconazole Capsule is distributed in New Zealand by:

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