

		Canesten Duo CMI 19 May 2009
	Consumer Medicine Information	

# Canesten® Fluconazole Capsule & Clotrimazole Cream Duo

**Fluconazole oral capsule 150 mg**  
**Clotrimazole topical cream 10 mg/g**

---

## What is in this leaflet

This leaflet answers some common questions about Canesten Fluconazole Capsule & Clotrimazole Cream Duo (referred to as Canesten Duo).

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 Duo 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 Duo is used for

Canesten Duo is used to treat a fungal infection in the vagina and vulval area (thrush). Canesten Duo contains two products: Canesten Fluconazole Capsule is an oral capsule which contains the active ingredient fluconazole; Canesten cream contains the active ingredient clotrimazole. Both of these medicines belong 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. Canesten cream provides soothing relief from external itching and irritation.

### ***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

		Canesten Duo CMI 19 May 2009
	<b>Consumer Medicine Information</b>	

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

Thrush may cause the following symptoms:

- vaginal itching
- 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 Duo is a “Pharmacist Only Medicine”. It is available without a doctor’s prescription, but your pharmacist’s advice is required.

---

## Before you use Canesten Duo

---

### ***When you must not use it***

**Do not use Canesten Duo if you have an allergy to:**

- any medicine containing *fluconazole*
- any medicine containing *clotrimazole*
- any other similar antifungals such as miconazole and ketoconazole
- 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 use Canesten Duo if you are taking cisapride (Prepulsid®) – a medicine used to treat stomach problems.**

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

		Canesten Duo CMI 19 May 2009
	<b>Consumer Medicine Information</b>	

**Canesten Duo 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 use 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 using this medicine, talk to your doctor or pharmacist.**

***Before you start to use it***

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

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

Canesten Duo 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 Duo 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 (the active ingredient in the capsule part of Canesten Duo).**

**Tell your doctor or pharmacist if you are taking warfarin (Marevan<sup>®</sup>, Coumadin<sup>®</sup>), 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 using Canesten Duo.**

		Canesten Duo CMI 19 May 2009
	<b>Consumer Medicine Information</b>	

### ***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 Duo may interfere with each other. These include:

- cisapride (Prepulsid®) – a medicine used to treat stomach problems. **Do not take Canesten Duo if you are taking cisapride.**
- some medicines used to treat diabetes such as tolbutamide, glimepiride, 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 Duo 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 Duo.

---

## **How to use Canesten Duo**

---

**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 use it***

**Wash your hands thoroughly before using Canesten Duo and after handling the Canesten cream.**

To avoid the possibility of re-infection, strict personal hygiene must be observed.

### **Canesten Fluconazole Capsule**

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 the Canesten Duo capsule, symptoms of thrush usually start to get better in about one day.

### **Canesten Cream**

Use the cream on the external irritated area 2-3 times a day to relieve the symptoms of itching or burning.

		Canesten Duo CMI 19 May 2009
	Consumer Medicine Information	

### ***When to use it***

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

Use Canesten cream for as long as you experience itching or your doctor or pharmacist tells you to. This cream helps to relieve the external symptoms of your condition.

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

**DO NOT TAKE THE CREAM BY MOUTH.**

### ***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 using Canesten Duo**

---

### ***Things you must do***

**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 Duo.**

**Use effective contraception to prevent pregnancy while taking Canesten Duo.**

### ***Things you must not do***

**Do not use Canesten Duo 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***

**The cream in Canesten Duo may reduce the effectiveness and safety of latex products, such as condoms and diaphragms.**

This effect is temporary and occurs only during treatment.

Canesten Duo 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.

		Canesten Duo CMI 19 May 2009
	<b>Consumer Medicine Information</b>	

- 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 using Canesten Duo.**

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.**

**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
- skin reaction to the cream (stinging, redness, blistering, peeling, swelling, itching)

The list above includes the more common side effects of Canesten Duo. 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

		Canesten Duo CMI 19 May 2009
	<b>Consumer Medicine Information</b>	

These side effects are rare but can be serious and 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 Duo**

---

### ***Storage***

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

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

**Keep your capsule and cream 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.

**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***

#### **Capsule**

The expiry date is marked on the foil/blister. The date refers to the month and year of expiration e.g. 0805 refers to the eighth month of 2005. The product can be used until the end of this month.

#### **Cream**

The expiry date is marked on the end panel of the carton and is also printed on the crimp at the end of the tube. The date refers to the month and year of expiration e.g. 0805 refers to the eighth month of 2005. The product can be used until the end of this month.

### ***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 Duo CMI 19 May 2009
	<b>Consumer Medicine Information</b>	

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

Canesten cream is a white opaque cream presented in a screw-cap tube containing 10 g of cream.

### ***Ingredients***

#### **Canesten Fluconazole Capsule & Clotrimazole Cream Duo.**

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

The cream contains 10 mg clotrimazole as the active ingredient in each gram of cream. It also contains:

- sorbitan monostearate
- Polysorbate 60
- cetyl palmitate
- cetostearyl alcohol
- octyldodecanol
- benzyl alcohol
- purified water

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

### ***Manufacturer***

Canesten Fluconazole Capsules are made in Canada.

Canesten cream is made in Spain.

Canesten Fluconazole Capsule & Clotrimazole Cream Duo is distributed in New Zealand by:



		<i>Canesten Duo CMI</i> <i>19 May 2009</i>
	<b>Consumer Medicine Information</b>	

Bayer New Zealand Limited  
 Consumer Care Business Group  
 3 Argus Place  
 Hillcrest  
 North Shore 0627  
 AUCKLAND  
 Toll Free: 0800 847 874

This leaflet was prepared on 19 May 2009.

**Reference: Canesten Fluconazole Capsule & Clotrimazole Cream Duo Data Sheet dated 2 April 2009.**

® = Registered Trademark