

Canesoral

Fluconazole

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about CANESORAL.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor or pharmacist has weighed the risks of you taking CANESORAL against the benefits expected for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

The information in this leaflet relates only to CANESORAL. It is not to be used in relation to any other product, which may also contain the same active ingredient.

What CANESORAL is used for

CANESORAL is used to treat a type of fungal infection called vaginal thrush.

CANESORAL contains the active ingredient fluconazole, which belongs to a group of medicines called azole antifungals. These medicines work by preventing the growth of these fungi causing your infection.

Ask your doctor or pharmacist if you have any questions about why CANESORAL has been recommended for you.

Your doctor or pharmacist may have recommended CANESORAL for another reason.

CANESORAL is not recommended for children under 18 years of age except under doctor supervision.

There is no evidence that CANESORAL is addictive.

CANESORAL is a "Pharmacist Only Medicine". It is available without a doctor's prescription but your pharmacist's advice is required.

What is vaginal thrush

Vaginal thrush is a common name for vaginal candidiasis, an infection caused by a yeast-like fungus called *Candida*.

Candida is one of many organisms that live in the vagina. Your body's natural balance (immune system) normally keeps *Candida* under control, but when this natural balance is upset, *Candida* can multiply and can cause thrush symptoms.

Common symptoms of vaginal thrush include:

- itching, burning or soreness around the vagina
- cottage-cheese like discharge
- swelling or irritation of the infected area.

Things that may help you to avoid thrush in the future:

- wear cotton briefs, stockings and loose-fitting clothing rather than tight synthetic clothing
- wash regularly, but do not wash and dry yourself harshly
- avoid perfumed soaps, bath additives and vaginal deodorants.

Your doctor or pharmacist may have more information on things you can do to avoid thrush in the future.

Before you take CANESORAL

When you must not take it

Do not take CANESORAL if you are allergic to medicines containing:

- fluconazole
- other azole antifungals such as miconazole (eg. Daktarin), ketoconazole (eg. Nizoral), clotrimazole (eg. Canesten, Clonea), itraconazole (Sporanox)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath.

Do not take CANESORAL if you are taking cisapride (Prepulsid), a medicine used to treat stomach problems.

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

Do not take CANESORAL if you are pregnant; suspect you may be pregnant or if you may become pregnant during treatment.

CANESORAL should not be used during pregnancy as it may affect your developing baby.

Do not take CANESORAL if you are breastfeeding.

CANESORAL passes into breast milk and may affect your baby.

Do not take CANESORAL if the expiry date (EXP) printed on the pack has passed.

Do not take CANESORAL if the packaging shows signs of tampering or the capsule do not look quite right.

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

Before you start to take it

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

Tell your doctor or pharmacist if you have or have had, any medical conditions, especially the following:

- thrush more than twice in the last six months
- liver problems
- kidney problems
- heart problems
- HIV infection or AIDS.
- diabetes

Your doctor or pharmacist may want to take special care if you have any of these conditions.

Tell your doctor or pharmacist before using CANESORAL if you are taking warfarin (eg. Marevan, Coumadin), as bleeding or bruising may occur.

Tell your doctor or pharmacist if you are experiencing any of the following:

- Abnormal or irregular vaginal bleeding or blood stained discharge
- Foul smelling or unusual coloured discharge
- Vulval or vaginal sores, ulcers or blisters
- Lower abdominal pain or burning when passing urine
- Fever or chills

If you have not told your doctor or pharmacist about any of the above,

tell them before you start taking CANESORAL.

Taking other medicines

If you are taking cisapride (Prepulsid), a medicine used to treat stomach problems, do not take CANESORAL.

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

Some medicines may be affected by CANESORAL, or may affect how well it works. These include:

- warfarin (eg. Marevan, Coumadin), a medicine used to prevent blood clots
- phenytoin (Dilantin), a medicine used to treat epilepsy
- cyclosporin (eg. Neoral) or tacrolimus (Prograf), medicines used to prevent organ transplant rejection or to treat certain problems with the immune system
- certain medicines use to treat diabetes such as:
 - glibenclamide (eg. Daonil, Glimel), glipizide (Minidiab, Melizide), glimepiride (eg. Amaryl), gliclazide (eg. Diamicon, Glyade)
 - pioglitazone (Actos), rosiglitazone (Avandia)
- rifampicin (Rifadin, Rimycin) or rifabutin (Mycobutin), antibiotics used to treat infections
- theophylline (Nuelin), a medicine used to treat asthma
- midazolam (eg. Hypnovel) and triazolam (Halcion), medicines used as sedatives or to treat anxiety
- zidovudine (eg. Retrovir), a medicine used to treat AIDS patients
- hydrochlorothiazide (eg. Dithiazide), a medicine used for treating fluid problems and high blood pressure

- the contraceptive pill (birth control pill).

Talk to your doctor about the need for an additional method of contraception while taking CANESORAL.

CANESORAL may decrease the effectiveness of some birth control pills.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking CANESORAL.

How to take CANESORAL

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

For vaginal thrush in adults, only a single dose (1 capsule) of CANESORAL is needed.

Do not give CANESORAL to children under 18 years of age except under doctor supervision.

How to take it

Swallow the capsule whole with a glass of water.

How to take CANESORAL

CANESORAL can be taken with or without food.

If you take too much CANESORAL (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much CANESORAL.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking CANESORAL

Things you must do

Before starting any new medicine, tell your doctor or pharmacist that you are taking or have taken CANESORAL.

Tell all the doctors, dentists and pharmacists who are treating you that you are taking or have taken CANESORAL.

Use effective contraception to prevent pregnancy while taking CANESORAL.

Immediately tell your doctor if you do become pregnant while taking CANESORAL.

If your symptoms do not improve after 3 days, tell your doctor or pharmacist.

Things you must not do

Do not use CANESORAL to treat any other conditions unless your doctor or pharmacist tells you to.

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

Things to be careful of

Tell your doctor immediately if you develop a rash while taking CANESORAL.

People with AIDS or a weak immune system may be more prone to serious side effects of the skin.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking CANESORAL.

CANESORAL helps most people and is generally well tolerated. However it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by this list of possible 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 (feeling sick), vomiting
- stomach pain, indigestion
- diarrhoea
- headache.

The side effects listed above are common and usually mild.

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

- unusual muscle stiffness causing poor control of movement
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal

- passing more urine than normal, kidney pain (pain on the sides of the body)
- symptoms of liver disease such as yellowing of the skin or eyes; dark urine, pale stools; loss of appetite; unusual tiredness
- an irregular heart beat or palpitations.

These side effects are serious and need medical attention.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- signs of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
- severe blisters and bleeding of the lips, eyes, mouth, nose and genitals
- a severe rash with skin peeling, fever, chills and aching muscles.

These side effects are rare, but very serious and require urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

After taking CANESORAL

Storage

Keep CANESORAL 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.

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

Do not store CANESORAL or any other medicine in the bathroom or near a sink.

Do not leave your medicine in the car or on windowsills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor or pharmacist tells you to stop taking CANESORAL, or your medicine has passed its expiry date, ask your pharmacist what to do.

Product description

What it looks like

CANESORAL is a hard white gelatin capsule, marked with "G" and "FC 150" in black ink.

Each pack contains 1 capsule.

Ingredients

The active ingredient in CANESORAL is fluconazole 150 mg.

Each capsule also contains the following inactive ingredients:

- gelatin
- lactose
- maize starch
- silicon dioxide
- magnesium stearate
- sodium lauryl sulfate
- titanium dioxide (E171)
- TekPrint SW-9008 Black Printing Ink
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Supplier

CANESORAL is supplied in Australia by:

Bayer Australia Limited
ABN 22 000 318 714
Consumer Care Business Group
875 Pacific Highway
Pymble NSW 2073
Phone: 1800 023 884

CANESORAL is supplied in New Zealand by:

Bayer New Zealand Limited
Consumer Care Business Group
Argus Place
Glenfield, Auckland
Phone: 0800 847 874
AUST R 163215

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