

APO-FLUCONAZOLE

Contains the active ingredient, fluconazole

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine. Ask your doctor or pharmacist if you do not understand anything or are worried about taking your medicine.

This leaflet answers some common questions about fluconazole.

It does not contain all the available information.

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

The information in this leaflet was last updated on the date listed on the last page. Some more recent information on your medicine may be available. Speak to your pharmacist or doctor to obtain the most up-to-date information.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine against the benefits they expect it will have for you.

Keep this leaflet with your medicine.

You may want to read it again.

What fluconazole is used for

The name of your medicine is Apo-Fluconazole. It contains the active ingredient, fluconazole.

It is used to treat fungal and yeast infections and prevent them coming back.

How it works

Fluconazole belongs to a group of medicines called azole antibiotics.

It works by preventing the growth of the fungal and yeast organisms causing your infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed fluconazole for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery, but it may cause dizziness light-headedness or drowsiness (rarely) in some people. If any of these occur, do not drive, operate machinery or do anything else that could be dangerous.

Use in children

This medicine is not suitable for children weighing under 35 kg.

Before you take fluconazole

When you must not take it

Do not take this medicine if you have had an allergic reaction to:

- any medicine containing fluconazole
- medicines related to fluconazole such as itraconazole, miconazole, ketoconazole or clotrimazole
- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; muscle pain or tenderness or joint pain or rash, itching or hives on the skin.

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

Do not take this medicine after the expiry date (EXP) printed on the pack.

If you take this medicine after the expiry date has passed, it may not work as well.

Do not take this medicine if the packaging is torn, shows signs of tampering or if it does not look quite right.

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.

Before you start to take it

Tell your doctor if:

1. You have allergies to:

- any other medicines
- any other substances, such as foods, preservatives or dyes.

2. You have or have had any medical conditions, especially the following:

- liver problems
- heart problems
- kidney problems

- electrolyte imbalance.

3. You are pregnant or plan to become pregnant

Your doctor will discuss the risks and benefits of taking this medicine during pregnancy.

4. You are breast-feeding or plan to breast-feed.

Fluconazole passes into breast milk. Your doctor will discuss the risks and benefits of taking this medicine when breast-feeding.

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines and fluconazole may interfere with each other. These include:

- Cisapride, a medicine used for stomach problems. (you must not take cisapride with fluconazole)
- medicines called sulphonylureas, taken by mouth for diabetes, such as glipizide, tolbutamide or glibenclamide
- certain antibiotics and antiviral drugs such as rifampicin, rifabutin or zidovudine

- carbamazepine, used to treat epilepsy and conditions such as bipolar disorder
- some drugs which affect the immune system, such as cyclosporin or tacrolimus
- warfarin and other medicines used to prevent blood clots
- phenytoin, used to treat epilepsy
- theophylline, used to treat asthma
- some benzodiazepines such as midazolam, used for sedation and for treating seizures
- hydrochlorothiazide ("water" tablets, used for helping to lower blood pressure)
- any medicine which may affect the heart by causing QT-interval prolongation (your doctor or pharmacist will tell you).

These medicines may be affected by fluconazole or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist can tell you if you are taking any of these medicines. They may also have more information on other medicines to be careful with or avoid while taking fluconazole.

Other interactions not listed above may also occur.

How to take this medicine

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

They may be different to the information in this leaflet.

If you do not understand any written instructions, ask your doctor or pharmacist for help.

How much to take

Your doctor or pharmacist will tell you how many capsules you will need to take. This depends on your condition and whether or not you are taking any other medicines.

If you are taking a dose of less than 200 mg you will need to use a different brand of fluconazole.

Adults and the Elderly

The dose will depend on your infection and how you respond to fluconazole. It usually ranges from 50 mg to 400 mg once daily.

If you have kidney problems your doctor may modify the dose.

Children

This medicine is not suitable for children weighing under 35 kg. The dose for a child will depend on body weight and usually ranges from 3 mg to 12 mg per kg of body weight. However, depending on how serious the infection is, how the

child reacts to the medicine, and whether the child has any other medical conditions such as kidney problems, the doctor may tell you to give a different dose.

How to take it

Swallow the capsules whole with water.

When to take it

Take it at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How long to take it for

Continue taking your medicine until you finish the pack or for as long as your doctor tells you.

The length of time you take fluconazole will depend on the sort of infection you have.

Patients with a weakened immune system or those with difficult infections may need long-term treatment to prevent the infection from returning.

Make sure you have enough to last over weekends and holidays.

Do not stop taking fluconazole because you are feeling better.

If you do not complete the full course prescribed by your doctor, the infection may not clear completely or your symptoms may return.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice, or go to the Accident and Emergency Department at the nearest hospital, if you think that you or anyone else may have taken too much fluconazole.

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

You may need urgent medical attention.

If you take too much fluconazole, you may have hallucinations or extreme examples of side effects (see "Side effects of fluconazole").

While you are taking fluconazole

Things you must do

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking fluconazole.

If you are a woman of child-bearing age, you should avoid becoming pregnant or breast-feeding while taking Apo-Fluconazole.

Tell your doctor immediately if you become pregnant.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are taking fluconazole.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Go to your doctor regularly for a check-up.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

Do not stop taking this medicine or change the dosage without checking with your doctor.

If you do not complete the full course prescribed by your doctor, all of the organisms causing your infection may not be killed. These organisms may continue to grow and multiply so that your infection may not clear completely or may return.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not take your medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Things to be careful of

Be sure to follow your doctor's advice if regular checks on your liver are recommended.

In rare cases, fluconazole may affect the liver and may need to be stopped.

If you develop a severe skin rash while taking this medicine (especially if you suffer from HIV or have a weakened immune system), tell your doctor immediately.

If this rash worsens, this medicine may need to be stopped.

Be careful while driving or operating machinery until you know how fluconazole affects you.

Fluconazole may cause dizziness, light-headedness or drowsiness (rarely) in some people. If any of these occur, do

not drive, operate machinery or do anything else that could be dangerous.

Side effects of fluconazole

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time, they are not. Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

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

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

Following is a list of possible side effects. Do not be alarmed by this list. You may not experience any of them.

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

- nausea (feeling sick), vomiting (being sick), , strange taste, loss of appetite
- headache
- stomach pain, indigestion, diarrhoea or loose stools
- dry or sore mouth, constipation, wind
- dry skin, hair loss

- flushing or hot flushes

The above list includes the more common side effects. Mostly, these are mild.

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

- skin rash, itching skin or genitals, hives, strange skin odour
- numbness, tingling, pins and needles
- menstrual, vaginal or sexual problems
- increased restlessness, muscle tone or strength
- excessive urine, kidney pain
- sore throat or mouth, cold sores
- dizziness, giddiness, sight problems, hearing problems
- feeling thirsty, fatigued, sleepy or lethargic
- shivering or pain
- back pain, problems sleeping, nervousness
- abnormal blood tests which indicate lowered amounts of blood cells, raised cholesterol, triglycerides or liver enzymes, or lowered potassium

- high blood pressure, which is hard to feel but may be a cause of prolonged headache, dizziness, blurred vision or nausea
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- swelling of the face or other parts of the body due to fluid
- symptoms such as feeling tired, faint, short of breath or swelling due to fluid, which may be due to a condition called cardiomyopathy
- itchy skin, pale stools, dark urine; all symptoms of a problem with your gall bladder.

These may be serious side effects. You may need medical attention.

If any of the following happen, stop taking your medicine and either tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing, shortness of breath, difficulty with breathing, wheezing, asthma, sudden or severe itching, skin rash, hives (allergic reactions)

- blisters or flaking of large areas of skin , perhaps also with a fever
- fainting, feeling confused, passing out, seizures or fits
- yellowing of the skin or eyes, also called jaundice
- itchy skin, pale stools, dark urine; all symptoms of a problem with your gall bladder or liver
- fast or irregular heart beat
- severe abdominal cramps

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients.

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

After taking this medicine

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take the capsules out of their original packaging they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25 degrees C.

Do not store your medicine, or any other 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 it 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.

Disposal

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

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

Product description

What Apo-Fluconazole looks like

Apo-Fluconazole 50 mg capsules (not available):

Blue and white opaque capsules

Blister packs of 28 capsules.

Apo-Fluconazole 200 mg capsules:

Violet and white opaque capsules

Blister packs of 28 capsules.

Ingredients

Each capsule contains 50 mg or 200 mg of fluconazole as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- pregelatinised maize starch
- sodium lauryl sulfate
- colloidal anhydrous silica
- magnesium stearate
- purified talc.

The capsule shells contain

- gelatin
- sodium lauryl sulfate
- titanium dioxide (E171)

- brilliant blue FCF (E133)
- erythrosine (E127).

This medicine is gluten-free, sucrose-free, tartrazine-free and free from other azo dyes.

Australian Registration Numbers

Apo-Fluconazole 50 mg capsules (not available):

AUST R Number: 151629

Apo-Fluconazole 200 mg capsules:

AUST R Number: 151630

Distributor

Apotex Pty Ltd

66 Waterloo Road

North Ryde, NSW 2113

Australia

Apotex Pty Ltd is the licensee of the registered trade marks AX logo, APO and APOTEX from the registered proprietor, Apotex Inc.

This leaflet was prepared in:

March 2010.