

FLUCONAZOLE APOTEX

Fluconazole

Consumer Medicine Information

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

What is in this leaflet

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.

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

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

Keep this leaflet with the medicine.

You may need to read it again.

What this medicine is used for

Fluconazole is used to treat some types of fungal and yeast infections. It belongs to a group of medicines called azole antifungals.

How it works

Fluconazole works by preventing the growth of the fungi and yeast that have caused your infection.

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

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- fluconazole
- other antifungal agents, such as itraconazole or 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 take fluconazole if you are also taking any of the following medicines:

- terfenadine
- cisapride
- astemizole
- erythromycin
- pimozide
- quinidine

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.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- liver, kidney or heart problems
- severe skin allergies, such as Stevens-Johnson syndrome and toxic epidermal necrosis
- adrenal gland problems
- rare hereditary problems of galactose intolerance, Lapp-lactase deficiency or glucose-galactose malabsorption

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

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 get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines must not be taken at the same time as fluconazole. These include:

- cisapride, used to treat reflux
- astemizole or terfenadine, used to treat allergies
- pimozide, used to reduce uncontrolled movements (tics)
- erythromycin, used to treat infections
- quinidine, used to treat arrhythmias

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

- certain medicines for diabetes (e.g. glipizide or glibenclamide)
- certain medicines used to treat cholesterol (e.g. atorvastatin, simvastatin)
- certain antibiotics, antiviral and antifungal drugs (e.g. rifampicin, rifabutin, zidovudine, saquinavir, halofantrine, amphotericin B, voriconazole)
- certain medicines used to treat for heart problems (e.g. nifedipine, amlodipine, felodipine, amiodarone)
- certain drugs used in organ transplant patients (e.g. cyclosporin, prednisone, tacrolimus, sirolimus, tofacitinib)
- cyclophosphamide and vinca alkaloids, used to treat cancer
- anticoagulants used to prevent blood clots (e.g. warfarin)
- phenytoin and carbamazepine, used to treat epilepsy
- theophylline, used to treat asthma
- certain anti-anxiety or sedative medicines (e.g. midazolam)
- hydrochlorothiazide, used to treat excess fluid

- contraceptive medicine
- NSAIDS (e.g. naproxen, diclofenac, celecoxib)
- opioid pain killers (e.g. alfentanil, fentanyl or methadone)
- losartan, used to treat high blood pressure
- vitamin A
- antidepressants (e.g. amitriptyline, nortriptyline)

These medicines may be affected by this medicine 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 have more information on medicines to be careful with or avoid while taking this medicine.

How to take this medicine

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 on the box/bottle, ask your doctor or pharmacist for help.

How much to take

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

How to take it

Swallow the capsules whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it 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 this medicine before or after food.

How long to take it

Continue taking your medicine 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.

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 to take 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.

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 (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are using this medicine

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

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

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

Do not stop taking your medicine or lower 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.

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 suffer from HIV or have a weakened immune system and develop a rash while taking fluconazole, tell your doctor immediately.

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

Be careful driving or operating machinery until you know how this medicine affects you.

This medicine may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

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

This medicine helps most people with fungal and yeast infections, 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 lists 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 vomiting
- headache
- dizziness
- stomach pain, indigestion, diarrhoea

The above list includes the more common side effects of your

medicine. They are usually mild and short-lived.

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

- flaking of the skin
- hair loss
- yellowing of the skin or eyes (jaundice)
- bleeding or bruising more easily than normal, reddish or purplish blotches under the skin
- fast or irregular heart beat
- increased sweating

The above list includes serious side effects that may require medical attention.

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

- signs of an allergic reaction, including swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; sudden or severe itching, skin rash, hives; asthma, wheezing, shortness of breath
- fainting, seizures or fits
- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers

The above list includes very serious side effects. You may need 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.

Storage and Presentation

Storage

Keep your capsules in the pack until it is time to take them.

If you take the capsules out of the pack, they may not keep well.

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

Do not store this 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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

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

Sponsor

This medicine is sponsored in Australia by:

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park NSW 2113

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Product description

What it looks like

Purple/white hard gelatin, self-locked capsules of size '0' containing white to off white powder.

Blister (PVC/PVDC/Al) containing 28 capsules per pack.

AUST R: 293315

Ingredients

This medicine contains 200 mg of fluconazole as the active ingredient.

This medicine also contains the following:

- lactose monohydrate
- maize starch
- colloidal anhydrous silica
- magnesium stearate
- sodium lauryl sulfate.

Capsule shell composition:

- patent blue V
- titanium dioxide
- gelatin
- erythrosine
- purified water.