

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.

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. More recent information on your medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

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

It is used to treat certain fungal and yeast infections.

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

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

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.

There is no evidence that this medicine is addictive.

Use in children

This medicine is not suitable for children weighing less than 35 kg.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- You are taking terfenadine (a medicine used to treat allergies). If you are receiving fluconazole doses of 400 mg or

more a day, you must not take terfenadine.

- You are taking medications that prolong the QT interval, such as cisapride, astemizole, primozide and quinidine.
- You are hypersensitive to, or have had an allergic reaction to, fluconazole, related medicines such as itraconazole, miconazole, ketoconazole or clotrimazole, or 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.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or if it does not look quite right.

Before you start to take it

Before you start taking this medicine, 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 currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
 4. You are currently breastfeeding or you plan to breast-feed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
 5. You are planning to have surgery or an anaesthetic.
 6. You are currently receiving or are planning to receive dental treatment.
 7. You are taking or planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with fluconazole. These include:

- some medicines used for heart problems, such as verapamil
- hydrochlorothiazide ("water" tablets, used for helping to lower blood pressure)
- certain antibiotics, antiviral and antifungal drugs such as, rifampicin, rifabutin, zidovudine, amphotericin B, erythromycin, and voriconazole
- medicines called sulphonylureas, taken by mouth for diabetes, such as glipizide, tolbutamide and glibenclamide
- some benzodiazepines such as midazolam, used for sedation and for treating seizures

- carbamazepine, used to treat epilepsy and conditions such as bipolar disorder
- some drugs which affect the immune system, such as cyclosporin, tacrolimus, sirolimus, or tofacitinib
- phenytoin, used to treat epilepsy
- theophylline, used to treat asthma
- warfarin and other medicines used to prevent blood clots
- the contraceptive pill (birth control pill)
- medicines which may affect the heart by causing QT-interval prolongation, such as cisapride, astemizole, pimozide and quinidine
- terfenadine, a medicine used to treat allergies
- cyclophosphamide (used to treat certain types of cancers)
- NSAIDS such as naproxen, diclofenac and celecoxib
- opioid pain killers such as alfentanil, fentanyl and methadone
- losartan (used for treating high blood pressure)
- antidepressants such as amitriptyline and nortriptyline.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with fluconazole.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on whether you are taking any other medicines.

For children, the dose is also dependent on the weight of the child.

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

How to take it

Swallow the capsules whole with water.

When to take it

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and 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 for as long as your doctor tells you.

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

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

This may increase the chance of you experiencing side effects.

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

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

If you are a woman of child-bearing age, you should avoid becoming pregnant while taking fluconazole.

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

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

Tell any doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

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 you develop a rash while taking fluconazole, tell your doctor immediately.

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking fluconazole or if you have any questions or concerns.

Do not be alarmed by the following list of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

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

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

These may be serious side effects and you may need medical attention.

- yellowing of the skin or eyes, also called jaundice
- 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.

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency at your nearest hospital.

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

- seizures or fits
- blotches or flaking of the skin
- fast or irregular heart beat.

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

Allergic reactions

If you think you are having an allergic reaction to fluconazole, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

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

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°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 this medicine 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Fluconazole looks like

50 mg capsules: Blue and white opaque capsules.

Blister packs of 28 capsules.

200 mg capsules: Violet and white opaque capsules

Blister packs of 28 capsules.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

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

It also contains the following inactive ingredients:

- lactose monohydrate
- 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 of other azo dyes.

Australian Registration Numbers

APO-Fluconazole 50 mg capsules

AUST R 151629

APO-Fluconazole 200 mg capsules

AUST R 151630

Distributor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park, NSW 2113

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