

APO-Fluconazole One

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 APO-Fluconazole One. 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 this 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

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.

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

What this medicine is used for

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

It is used to treat a fungal infection known as vaginal thrush.

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

Use in children

This medicine is not recommended for children under 18 years of age, except under doctor advice.

APO-Fluconazole One is a "Pharmacist Only Medicine". It is available without a doctor's prescription but your pharmacist's advice is required.

How it works

The active ingredient in this medicine is fluconazole, which is classified with medicines known as azole antifungals. This group of antifungal medicines work by preventing the growth of the fungi causing your infection.

There is no evidence that this medicine is addictive.

What is vaginal thrush?

Vaginal candidiasis, an infection caused by a yeast-like fungus *Candida*, is commonly referred to as "vaginal thrush".

Candida is one of the many organisms that live in the vagina and its growth is normally balanced by your body's natural defence mechanism known as the 'immune system'. However, when this natural balancing is upset, *Candida* can multiply in the vagina to cause the symptoms of thrush.

Common symptoms of vaginal thrush include:

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

What you can do to avoid thrush in the future

- avoid wearing synthetic underwear
- wear loose-fitting cotton briefs, stockings
- wash the area regularly, but do not wash and dry yourself harshly
- avoid vaginal deodorants, perfumed soaps and bath additives.

Ask your doctor or pharmacist for more information for things you can do to avoid thrush in the future.

Before you take this medicine

When you must not take it

You have or have had any of the following

- **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.**

Fluconazole may affect your developing baby if you take it during pregnancy.

- **You are currently breast-feeding or you plan to breast-feed. Use during breastfeeding is not recommended, as fluconazole may pass into breast milk.**
- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.
- **You have had an allergic reaction to:**
 - medicines containing fluconazole
 - medicines related to fluconazole, such as miconazole (e.g. Daktarin), ketonazole (e.g. Nizoral), clotrimazole (e.g. Canesten, Clonea), or itraconazole (Sporanox)
 - any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include 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 or hayfever-like symptoms.

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.

Do not take this medicine if you are taking any of the following medicines:

- **cisapride (Prepulsid), a medicine used to treat stomach problems**
- **astemizole, an antihistamine**
- **erythromycin, an antibiotic**
- **quinidine, a medicine used to treat heart problems**
- **pimozide, a medicine used to treat certain mental and emotional conditions**
- **voriconazole, an antifungal medicine**

Combining fluconazole with these medicines may cause serious side effects, such as an abnormal heart rhythm.

Before you start to take it

Before you start taking this medicine, tell your doctor or pharmacist if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes
 - lactose, or galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption (this product contains lactose).
2. You have or have had any medical conditions, especially the following:
 - abnormal or irregular vaginal bleeding or blood stained discharge
 - vulvar or vaginal sores, ulcers or blisters
 - lower abdominal pain or burning when passing urine
 - any liver problems
 - any kidney problems
 - any heart problems.
3. You are planning to have an operation. Some medicines used during anaesthetics may interact with fluconazole.
4. You are taking or are 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:

Medicines not to be taken with fluconazole:

- cisapride (Prepulsid)- used to treat stomach problems.
- astemizole, an antihistamine
- quinidine, used to treat heart problems
- erythromycin, an antibiotic
- quinidine, a medicine used to treat heart problems
- pimozide, a medicine used to treat certain mental and emotional conditions
- voriconazole, an antifungal medicine

Medicines to be taken with care with fluconazole:

- terfenadine, an antihistamine
- some medicines used to treat diabetes, such as:
 - glipizide, chlorpropamide, tolbutamide, glibenclamide, glimepiride or gliclazide.
 - pioglitazone (Actos), rosiglitazone (Avandia)
- some antibiotics and antiviral drugs such as erythromycin, amphotericin B, rifampicin, rifabutin, zidovudine or saquinavir
- some medicines used in problems with the immune system, such as cyclosporine, tacrolimus or sirolimus
- cyclophosphamide, used to treat cancer and autoimmune disease
- vincristine and vinblastine, used to treat cancer
- vitamin A
- antidepressants such as amitriptyline and nortriptyline

- warfarin or ticlopidine, (used to stop blood clots)
- phenytoin and carbamazepine (used to treat epilepsy)
- theophylline (used to treat asthma)
- medicines used during anaesthetics such as alfentanil, midazolam and fentanyl (also used for pain)
- other benzodiazepines, such as triazolam (halcion)
- hydrochlorothiazide (dithiazide), used for treating fluid problems and high blood pressure
- medicines used to treat high blood pressure (e.g losartan, amlodipine and felodipine)
- medicines used to treat high cholesterol (e.g. simvastatin, fluvastatin, atorvastatin)
- methadone, used for pain relief and as a heroin replacement
- celecoxib, used for treating arthritis and pain
- halofantrine, used to treat malaria
- prednisone, a type of corticosteroid
- the contraceptive pill (birth control pill).

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

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 or pharmacist.

Their instructions may be different to the information in this leaflet.

How much to take

For vaginal thrush in adults, only a single dose (1 capsule) of APO-Fluconazole One is needed.

How to take it

Swallow the whole capsule with a glass of water.

When to take it

This medicine can be taken any time before, with or after food.

If you take too much APO-Fluconazole One (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 pregnant or are planning to become pregnant (use effective contraception and if you become pregnant tell your doctor immediately)

- you are breast-feeding or are planning to breast-feed

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

If the symptoms of your infection do not improve after 3 days, or if they become worse, tell your doctor or pharmacist.

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 or pharmacist tells you to

Things to be careful of

Tell your doctor or pharmacist immediately if you develop a rash soon after taking this medicine.

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

Possible side effects

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

This list includes the more common side effects. Mostly, these are mild:

- nausea or vomiting (feeling or being sick)
- stomach pain, indigestion, wind
- diarrhoea
- muscle or back pain
- headache.

Tell your doctor or pharmacist as soon as possible if you notice any of the following. These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- skin reactions/rash
- 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 - also called jaundice; dark urine, pale stools; loss of appetite; unusual tiredness

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

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

- fast, slow or irregular heart beat or palpitations and/or fainting.
- severe blisters and bleeding of the lips, eyes, mouth, nose and genitals
- a severe rash with skin peeling, fever, chills and aching muscles.

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
- hayfever-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 30°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.

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.

Product description

What APO-Fluconazole One looks like

A hard gelatine capsule of size '1' with sky blue body and cap.

Each pack contains 1 capsule.

Ingredients

Each capsule contains 150 mg of fluconazole as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- maize starch
- colloidal anhydrous silica
- purified talc
- sodium lauryl sulphate
- gelatin
- titanium dioxide
- patent blue colour E131

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

Australian Registration Numbers

APO-Fluconazole One 150 mg Capsule (blister pack): AUST R 152959.

Sponsor

Apotex Pty Ltd
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