

# APO-FLUCONAZOLE

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using APO-FLUCONAZOLE?

APO-FLUCONAZOLE contains the active ingredient fluconazole. APO-FLUCONAZOLE capsules are used to treat certain fungal and yeast infections.

For more information, see Section [1. Why am I using APO-FLUCONAZOLE?](#) in the full CMI.

### 2. What should I know before I use APO-FLUCONAZOLE?

Do not start treatment if you are allergic to any medicine containing fluconazole, any of the ingredients listed at the end of this CMI, or any other similar medicines such as miconazole, ketoconazole or clotrimazole. Tell your doctor if you have had any allergic reactions to any antifungal or any food, preservatives or dyes or any other medicines, if you are pregnant, plan to become pregnant or are breastfeeding. You must not be given APO-FLUCONAZOLE if you are taking certain medicines.

For more information, see Section [2. What should I know before I use APO-FLUCONAZOLE?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with APO-FLUCONAZOLE and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use APO-FLUCONAZOLE?

APO-FLUCONAZOLE is available as capsules which are swallowed whole with water. Your doctor will decide how much APO-FLUCONAZOLE will be given to you each day and for how long. It will depend on your condition and other factors.

More instructions can be found in Section [4. How do I use APO-FLUCONAZOLE?](#) in the full CMI.

### 5. What should I know while using APO-FLUCONAZOLE?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Tell the doctor if you have any medical conditions, are on any medicines, or if you are pregnant, plan to become pregnant or are breastfeeding.</li><li>• For more information on "Things you should do" can be found in Section 6 in the full CMI</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not start treatment if you have ever had an allergic reaction to any medicine containing fluconazole, any of the ingredients listed at the end of this CMI, or any other similar medicines such as miconazole, ketoconazole or clotrimazole.</li><li>• Do not stop taking APO-FLUCONAZOLE or lower the dosage without checking with your doctor.</li><li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li><li>• Do not use APO-FLUCONAZOLE to treat any other medical complaints unless your doctor tells you to.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your medicine in a cool dry place where the temperature stays below 25°C.</li><li>• Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it in the bathroom or near a sink, or in the car or on window sills.</li><li>• Do not use this medicine after expiry date</li></ul>

For more information, see Section [5. What should I know while using APO-FLUCONAZOLE?](#) in the full CMI.

### 6. Are there any side effects?

APO-FLUCONAZOLE is generally well tolerated. Side effects may include nausea, vomiting, abdominal pain, diarrhoea, headache, skin rash or redness and easy bruising of the skin, seizures, signs of frequent or worrying infections such as fever, severe chills, sore throat, or mouth ulcers, or change in liver function.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# APO-FLUCONAZOLE

Active ingredient(s): *Fluconazole*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-FLUCONAZOLE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-FLUCONAZOLE.**

**Where to find information in this leaflet:**

- [1. Why am I using APO-FLUCONAZOLE?](#)
- [2. What should I know before I use APO-FLUCONAZOLE?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-FLUCONAZOLE?](#)
- [5. What should I know while using APO-FLUCONAZOLE?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using APO-FLUCONAZOLE?

APO-FLUCONAZOLE is used to treat certain fungal and yeast infections.

APO-FLUCONAZOLE belongs to a group of medicines called azole antibiotics. It works by preventing the growth of the fungal and yeast organisms causing your 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.

This medicine is not addictive.

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

## 2. What should I know before I use APO-FLUCONAZOLE?

### Warnings

**Do not use APO-FLUCONAZOLE if:**

- you are allergic to fluconazole, or any of the ingredients listed at the end of this leaflet, or related to any medicines such as miconazole, ketoconazole or clotrimazole.
- 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 use APO-FLUCONAZOLE if you are taking any of the following medicines:**

- terfenadine or astemizole (a medicine used to treat allergies).
- cisapride (a medicine used to treat stomach problems)
- erythromycin (a medicine used to treat infections)
- primozide (a medicine used to treat mental illness)
- quinidine (a medicine used to treat irregular heartbeat).

**Check with your doctor if:**

- have allergies to any other substances, such as foods, preservatives, or dyes.
- are taking medicines for any other conditions
- have other medical conditions
- have liver problems
- have heart problems
- have kidney problems

Your doctor may need to monitor the function of the liver using blood tests. Be sure to follow the doctor's advice if regular checks on your liver are recommended.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

APO-FLUCONAZOLE use should be avoided during pregnancy except on doctor's advice for severe or life-threatening infections. Effective contraception should be used in women of childbearing potential and should continue throughout the treatment period and for approximately 1 week after the final dose. Your doctor can discuss with you the risks and benefits involved.

**Talk to your doctor about the need for an additional method of contraception while being given APO-FLUCONAZOLE.**

APO-FLUCONAZOLE may decrease the effectiveness of some birth control pills.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

APO-FLUCONAZOLE is not recommended for use whilst breastfeeding however your doctor can discuss with you the risks and benefits involved.

### 3. What if I am taking other medicines?

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

**Some medicines may interfere with APO-FLUCONAZOLE and affect how it works.**

These are listed under Section 2.

#### **What should I know before treatment with APO-FLUCONAZOLE.**

Some medicines and APO-FLUCONAZOLE may interfere with each other. These medicines and some others may be affected by APO-FLUCONAZOLE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. These include:

- some medicines for diabetes such as glipizide, tolbutamide or glibenclamide
- some antibiotics, antiviral and antifungal drugs such as rifampicin, rifabutin, zidovudine, amphotericin B, azithromycin, saquinavir or voriconazole
- some medicines used for heart problems, such as amiodarone or verapamil
- some drugs which affect the immune system, such as ciclosporin, everolimus, tacrolimus, sirolimus, or tofacitinib
- some medicine use to lower cholesterol such as atorvastatin, simvastatin or Fluvastatin
- abrocitinib, used to treat atopic dermatitis (atopic eczema)
- cyclophosphamide, vincristine, vinblastine, Olaparib or ibrutinib (use to treat certain types of cancer)
- tolvaptan (used to treat low levels of sodium in your blood or for kidney problems)
- halofantrine (used to treat malaria)
- warfarin and other medicines used to prevent blood clots
- phenytoin, used to treat epilepsy
- prednisone (used to treat inflammation or suppress the immune system)
- theophylline, used to treat asthma
- some benzodiazepines such as midazolam
- lemborexant (used to treat insomnia or sleeping difficulties)
- ivacaftor (used to manage cystic fibrosis)
- lurasidone (used to manage schizophrenia)
- hydrochlorothiazide (used for treating fluid problems)
- the contraceptive pill (birth control pill)
- carbamazepine, used to treat epilepsy and conditions such as bipolar disorder

- NSAIDS such as naproxen, diclofenac and celecoxib
- Vitamin A
- opioid pain killers such as alfentanil, fentanyl and methadone
- losartan (used for treating high blood pressure)
- antidepressants such as amitriptyline and nortriptyline.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-FLUCONAZOLE.**

### 4. How do I use APO-FLUCONAZOLE?

#### **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.

#### **When to take APO-FLUCONAZOLE**

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 to take it**

Swallow the capsules whole with water.

#### **How long to take it**

Continue taking APO-FLUCONAZOLE until you finish the pack or until your doctor recommends.

The length of time you take APO-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 your APO-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 APO-FLUCONAZOLE**

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

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

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

#### **If you use too much APO-FLUCONAZOLE**

If you think that you have used too much APO-FLUCONAZOLE, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre

(by calling 13 11 26), or

- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using APO-FLUCONAZOLE?

### Things you should do

- If you are a woman of child-bearing age, you should avoid becoming pregnant while taking APO-FLUCONAZOLE. Talk to your doctor about the need for an additional method of contraception while being given APO-FLUCONAZOLE.

If you do become pregnant while taking APO-FLUCONAZOLE, tell your doctor immediately.

- If you suffer from HIV or have a weakened immune system and develop a rash while taking APO-FLUCONAZOLE, tell your doctor immediately.

If this rash worsens, APO-FLUCONAZOLE may need to be stopped.

- Be sure to follow your doctor's advice if regular checks on your liver are recommended. In rare cases, APO-FLUCONAZOLE may affect the liver and may need to be stopped.
- If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.
- Remind any doctor, dentist, or pharmacist you visit that you are using APO-FLUCONAZOLE.

### Things you should not do

- Do not start treatment if you have ever had an allergic reaction to any medicine containing fluconazole, any of the ingredients listed at the end of this CMI
- Do not stop taking APO-FLUCONAZOLE or lower the dosage without checking with your doctor. If you do not complete the full course prescribed by your doctor, all 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 your medicine to anyone else, even if they have the same condition as you.
- Do not use APO-FLUCONAZOLE to treat any other medical complaints unless your doctor tells you to.

### Driving or using machines

Be careful before you drive operate machinery as occasional dizziness or seizures may occur.

### Drinking alcohol

No information available.

### Looking after your medicine

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

If you take it out of the pack it may not keep well. Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink,
- in the car or on window sills.

**Store APO-FLUCONAZOLE below 25°C.**

Do not use this medicine after the expiry date.

Keep it where young children cannot reach it.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• nausea or feeling sick, vomiting</li><li>• headache</li><li>• stomach pain, indigestion, diarrhoea</li><li>• acne</li><li>• blurred or abnormal vision</li><li>• hot flushes</li><li>• constipation</li><li>• low blood potassium which can result in fatigue, muscle cramps and abnormal heart rhythms*</li><li>• changes in liver function*</li></ul> <p>* These side effects may show up when you have a blood test.</p>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Allergy or reaction related:</b></p> <ul style="list-style-type: none"><li>• swelling of the face, lips or tongue</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at</b></p>

<ul style="list-style-type: none"> <li>• difficulty in swallowing or breathing</li> <li>• asthma, wheezing, shortness of breath</li> </ul> <p><b>Skin Changes:</b></p> <ul style="list-style-type: none"> <li>• yellowing of the skin or eyes, also called jaundice</li> <li>• sudden or severe itching, skin rash, or hives</li> <li>• bleeding or bruising more easily than normal</li> <li>• reddish or purplish blotches under the skin</li> <li>• flaking of the skin</li> </ul> <p><b>Changes to urine:</b></p> <ul style="list-style-type: none"> <li>• dark urine and light coloured bowel movements (cholestasis)</li> </ul> <p><b>Signs of frequent or worrying infections such as:</b></p> <ul style="list-style-type: none"> <li>• fever, severe chills, sore throat or mouth ulcers</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>• fainting, seizures or fits</li> <li>• fast or irregular heartbeat</li> <li>• increased sweating</li> </ul>	<p><b>your nearest hospital if you notice any of these serious side effects.</b></p>
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What APO-FLUCONAZOLE contains

<b>Active ingredient (main ingredient)</b>	Fluconazole
<b>Other ingredients</b>	<ul style="list-style-type: none"> <li>• lactose monohydrate</li> </ul>

<b>(inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• maize starch</li> <li>• colloidal anhydrous silica</li> <li>• magnesium stearate</li> <li>• sodium lauryl sulfate</li> </ul> <p>The capsule shells contain:</p> <ul style="list-style-type: none"> <li>• Patent blue V</li> <li>• titanium dioxide</li> <li>• gelatin</li> <li>• erythrosine</li> <li>• purified water</li> </ul>
<b>Potential allergens</b>	<p>Sugars as lactose</p> <p>May contain traces of sulfites and phenylalanine</p>

**Do not take this medicine if you are allergic to any of these ingredients.**

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

### What APO-FLUCONAZOLE looks like

**200 mg capsules** – Purple/ white hard gelatin self-locked capsules of size '0' containing white to off white powder.

AUST R – 293315

Available in blister packs of 28 capsules.

### Who distributes APO-FLUCONAZOLE

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

Web: [www.arrotex.com.au](http://www.arrotex.com.au)

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