

# APOHEALTH-Fluconazole -One

## 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 APOHEALTH-Fluconazole One?

APOHEALTH-Fluconazole-One contains the active ingredient Fluconazole. APOHEALTH-Fluconazole-One is used to treat a fungal infection known as vaginal thrush (vaginal candidiasis).

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

### 2. What should I know before I use APOHEALTH-Fluconazole-One?

Do not use if you have ever had an allergic reaction to Fluconazole or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

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

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

Some medicines may interfere with APOHEALTH-Fluconazole-One 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 APOHEALTH-Fluconazole-One?

- APOHEALTH-Fluconazole One should be taken as single dose of one capsule. The whole capsule is to be swallowed with one glass of water.

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

### 5. What should I know while using APOHEALTH-Fluconazole-One?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using APOHEALTH-Fluconazole One.</li><li>• Are about to be started on any new medicine, remind your doctor or pharmacist that you have taken this medicine.</li><li>• If you become pregnant while taking this medicine, tell your doctor immediately</li><li>• If the symptoms of your infections do not improve after 03 days, or if they become worse, tell your doctor or pharmacist</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not give this medicine to anyone else, even if they have the same condition as you.</li><li>• Do not take this medicine to treat any other complaint unless your doctor or pharmacist tells you to do.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your medicine in its pack until it is time to take it.</li><li>• If you take your medicine out of its pack it may not keep well.</li></ul>

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

### 6. Are there any side effects?

The common side effects include nausea, vomiting, stomach pain, indigestion, wind, diarrhoea, muscle or back pain and headache.

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.

# APOHEALTH-Fluconazole-One

Active ingredient(s): Fluconazole

## Consumer Medicine Information (CMI)

This leaflet provides important information about using APOHEALTH-Fluconazole-One. **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 APOHEALTH-Fluconazole One.**

Where to find information in this leaflet:

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

## 1. Why am I using APOHEALTH-Fluconazole-One?

**APOHEALTH-Fluconazole One contains the active ingredient Fluconazole.** Fluconazole belongs to a group of medicines known as azole antifungals. These medicines work by preventing the growth of the fungi causing your infection.

**APOHEALTH-Fluconazole-One is used to treat a fungal infection known as vaginal thrush (vaginal candidiasis).**

**What is vaginal thrush?**

Vaginal thrush is a common name for vaginal candidiasis, an infection caused by a yeast-like fungus called *Candida*. *Candida* is one of many organisms that live in the vagina. Your body's natural balance (immune system) normally keeps *Candida* under control, but when this natural balance is upset, *Candida* can multiply and can cause thrush symptoms.

**Common symptoms of vaginal thrush include:**

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

**Things that may help you to avoid thrush in the future:**

- wear cotton briefs, stockings and loose-fitting clothing rather than tight synthetic clothing
- wash regularly, but do not wash and dry yourself harshly

- avoid perfumed soaps, bath additives and vaginal deodorants.

Your doctor or pharmacist may have more information on things you can do to avoid thrush in the future.

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

There is no evidence that APOHEALTH-Fluconazole-One is addictive. "APOHEALTH-Fluconazole-One is a Pharmacist Only Medicine". It is available without a doctor's prescription but your pharmacist's advice is required.

## 2. What should I know before I use APOHEALTH-Fluconazole One?

### Warnings

**Do not use APOHEALTH-Fluconazole One if:**

- you are allergic to Fluconazole, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Any other azole antifungals related to fluconazole such as miconazole (e.g. Daktarin), ketoconazole (e.g. Nizoral), clotrimazole (e.g. Canesten, Clonea) or itraconazole (e.g. Sporanox).

Some of the symptoms of an allergic reaction may include

- Shortness of breath
- Wheezing or breathing difficulty
- Swelling of the face, lips, tongue, throat, or other parts of the body
- Rash, itching or hives on the skin.

**Do not use fluconazole if you are taking any of the following medicines:**

- astemizole (a medicine used to treat allergy)
- cisapride (a medicine used to treat stomach problems)
- erythromycin (a medicine used to treat infections)
- pimozide (a medicine used to treat infections)
- quinidine (a medicine used to treat irregular heartbeat)

**Check with your doctor or pharmacist if you:**

- have allergies to any other medicines, food, dyes or preservatives
- take any medicines for any other condition
- have liver problems
- have kidney problems
- have heart problems
- have HIV infection or AIDS

- have diabetes
- have had thrush more than twice in the last six months
- are over 60 years of age

#### **Tell your doctor or pharmacist if you:**

- are experiencing any of the following: abnormal or irregular vaginal bleeding or blood stained discharge; foul smelling or unusual coloured discharge; vulval or vaginal sores, ulcers or blisters; lower abdominal pain or burning when passing urine; fever or chills
- are taking warfarin, as bleeding or bruising may occur

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**

Do not use fluconazole if you are pregnant, suspect you may be pregnant or if you may become pregnant during treatment. Fluconazole may affect your developing baby if you take it during pregnancy. Your pharmacist will discuss with you the risks and benefits involved.

**Do not use this medicine if you are a female of childbearing age unless you are using adequate contraception.**

Effective contraception should be taken during treatment and for about 1 week after the final dose.

**Do not take this medicine if you are breast-feeding or intend to breastfeed.**

Fluconazole may pass into breast milk and affect your baby.

### **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 should not be taken with fluconazole.**

These are listed under Section [2. What should I know before I use APOHEALTH-Fluconazole One?](#)

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

- Amiodarone (used to treat irregular heartbeat)
- Some oral diabetes medication
- Some antibiotics such as rifampicin, rifabutin and azithromycin
- Some antiviral drugs used to treat HIV such as zidovudine and saquinavir
- Some antifungal drugs such as amphotericin B and voriconazole

- Some medicines used in problems with immune system, such as ciclosporin, tacrolimus, sirolimus, everolimus or tofacitinib
- cyclophosphamide, ibrutinib, Olaparib, vincristine, vinblastine (used to treat certain types of cancers)
- Vitamin A
- Antidepressants such as amitriptyline, nortriptyline
- predinsone (used to treat inflammation or suppress the immune system)
- lemborexant (used to treat insomnia or sleeping difficulties)
- Warfarin (used to stop blood clots).
- Phenytoin (used to treat epilepsy).
- carbamazepine (used in the treatment of epilepsy and bipolar disorder)
- Theophylline, used to treat asthma.
- Some opioid pain killers such as alfentanil, fentanyl and methadone
- Some benzodiazepines (used as sedatives or treat anxiety)
- Hydrochlorothiazide (used to treat fluid problems and high blood pressure)
- losartan (used for treating high blood pressure)
- calcium channel blockers such as nifedipine, amlodipine, felodipine and verapamil (used for relieving high blood pressure or irregular heart beat)
- statins such as simvastatin, Fluvastatin, atorvastatin (used to control high cholesterol levels)
- tolvaptan (used to treat low levels of sodium in your blood or for kidney problems)
- NSAIDS such as ibuprofen, naproxen, diclofenac and celecoxib
- lurasidone (used to manage schizophrenia)
- ivacaftor (used to manage cystic fibrosis)
- the contraceptive pill (birth control pill)

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

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

### **4. How do I use APOHEALTH-Fluconazole One?**

#### **How much to take / use**

- Follow all directions given to you by your pharmacist carefully.
- They may differ to this information contained in this leaflet.
- Follow the instructions provided and use APOHEALTH-Fluconazole One until your doctor tells you to stop.

## When to take / use APOHEALTH-Fluconazole

- APOHEALTH-Fluconazole One should be taken as single dose of one capsule.
- The whole capsule is to be swallowed with one glass of water.
- It does not matter whether you take this medicine with or without food.

## If you forget to use APOHEALTH-Fluconazole One

APOHEALTH-Fluconazole One should be used regularly at the same time each day. If you miss your dose at the usual time, take immediately before the next dose.

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

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

## If you use too much APOHEALTH-Fluconazole One

If you think that you have used too much APOHEALTH-Fluconazole One, 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 APOHEALTH-Fluconazole One?

### Things you should do

**Call your doctor straight away if you:**

- Are about to be started on any new medicine, remind your doctor or pharmacist that you have taken this medicine.
- Tell any other doctors, dentists and pharmacists who are treating you that you have taken this medicine.
- If you become pregnant while taking this medicine, tell your doctor immediately.
- If the symptoms of your infections do not improve after 03 days, or if they become worse, tell your doctor or pharmacist.

Remind any doctor, dentist, or pharmacist you visit that you are using APOHEALTH-Fluconazole One.

### Things you should not do

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not take this medicine to treat any other complaint unless your doctor or pharmacist tells you to do.

## Things to be careful of

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

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

## Driving or using machines

**Be careful before you drive or use any machines or tools until you know how APOHEALTH-fluconazole One affects you.**

Fluconazole may cause occasional dizziness or seizures in some people.

## Drinking alcohol

**Tell your doctor if you drink alcohol.**

No information on alcohol consumption with APOHEALTH-Fluconazole One.

## Looking after your medicine

- Keep your medicine in its pack until it is time to take it.
- If you take your medicine out of its pack it may not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

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.

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

**Heat and dampness can destroy some medicines.**

**Keep it where young children cannot reach it.**

**A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.**

## 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.

Do not use this medicine after the expiry date.

## 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>• Stomach pain, indigestion, diarrhoea</li><li>• Acne</li><li>• Blurred or abnormal vision</li><li>• Hot flushes</li><li>• Constipation</li><li>• Rash and itching</li><li>• headache</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

## 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><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>• Sudden or severe itching, skin rash, 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>• passing more urine than normal, kidney pain (pain on the sides of the body)</li></ul> <p><b>Signs of liver disease:</b></p> <ul style="list-style-type: none"><li>• dark urine, light coloured bowel movements (cholestasis)</li><li>• Yellowing of the skin and eyes (jaundice)</li><li>• loss of appetite, fatigue</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><li>• unusual muscle stiffness causing poor control of movement</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**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

### What APOHEALTH-Fluconazole One contains

<b>Active ingredient (main ingredient)</b>	Fluconazole
<b>Other ingredients (inactive ingredients)</b>	Lactose monohydrate Maize starch Colloidal anhydrous silica Purified talc Sodium lauryl sulphate Gelatin Titanium dioxide Patent blue V
<b>Potential allergens</b>	Contains sugars (as lactose) and sulfites

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

This medicine contains sugars (as lactose) and sulfites.

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

### What APOHEALTH-Fluconazole One looks like

APOHEALTH-Fluconazole One is a hard gelatin capsule of size "1" with a sky blue body and cap (Aust R 152959).

### Who distributes APOHEALTH-Fluconazole One

Arrotex Pharmaceuticals Pty Ltd  
15 – 17 Chapel Street  
Cremorne VIC 3121  
Australia  
Web: [www.arrotex.com.au](http://www.arrotex.com.au)

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