

PHARMANIAGA FLUCONAZOLE CAPSULE

Fluconazole (100mg, 150mg)

What is in this leaflet

1. What Pharmaniaga Fluconazole Capsule is used for
2. How Pharmaniaga Fluconazole Capsule works
3. Before you use Pharmaniaga Fluconazole Capsule
4. How to use Pharmaniaga Fluconazole Capsule
5. While you are using it
6. Side effects
7. Storage and Disposal of Pharmaniaga Fluconazole Capsule
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision

What Pharmaniaga Fluconazole Capsule is used for

Pharmaniaga Fluconazole Capsule is one of a group of medicines called 'antifungals'. The active substance is fluconazole. This medicine is used in adults to treat infections caused by fungi. The most common cause of fungal infections is a yeast called Candida.

How Pharmaniaga Fluconazole Capsule works

It works by preventing the growth of the fungal and yeast organisms causing your infection.

Before you use Pharmaniaga Fluconazole Capsule

-When you must not use it

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

- fluconazole, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description.
- any other similar antifungal medicines such as miconazole, ketoconazole or clotrimazole.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue

- rash, itching or hives on the skin.

Do not take this medicine if you are taking:

- cisapride, a medicine used to treat stomach problems.
- terfenadine, a medicine used to treat allergies, and you are taking Pharmaniaga Fluconazole Capsule at a dose of 400mg a day or higher.

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 or have had any of the following medical conditions:

- liver problems
- develop severe skin reactions (itching, reddening of the skin)

Before you use Pharmaniaga Fluconazole Capsule, inform your doctor if you have such conditions:

- Pregnant or planning to become pregnant
 - Pharmaniaga Fluconazole Capsule may cause harm to your unborn baby. You should not take Pharmaniaga Fluconazole Capsule while you are pregnant unless your doctor has told you to. Inform your doctor if you are pregnant or planning to become pregnant.
 - If you are a woman of child-bearing potential, avoid become pregnant during treatment. Use effective contraception during treatment and for 1 week after treatment.

- Breastfeeding
 - Pharmaniaga Fluconazole Capsule is excreted in human breast milk, hence its use in nursing mothers is not recommended. However, breast-feeding may be maintained if you took a single dose of Pharmaniaga Fluconazole Capsule 150mg. Breast-feeding is not recommended after a high dose (more than 150mg) or repeated use of Pharmaniaga Fluconazole Capsule.

Your doctor can discuss with you the risks and benefits involved. If you have not told your doctor about any of the above, tell him/her before you start taking Pharmaniaga Fluconazole Capsule.

-Taking other medicines

Some medicines and Pharmaniaga Fluconazole Capsule may interfere with each other. These include:

- anticoagulant medicine
- medicines used to control allergies
- terfenadine, medicines used to control allergies
- cisapride, a medicine used to treat stomach problems
- phenytoin, medicines used to control epilepsy
- theophylline, a medicine used to treat asthma
- hydrochlorothiazide, used for treating fluid problems or to treat high blood pressure
- birth control pills
- medicines used to control the immune system such as cyclosporine and tacrolimus.
- some antiviral and antibiotic medicines such as rifampicin, rifabutin and zidovudine.

These medicines may be affected by Pharmaniaga Fluconazole Capsule or may affect how well it works. You may need different amounts of your

PHARMANIAGA FLUCONAZOLE CAPSULE

Fluconazole (100mg, 150mg)

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 use Pharmaniaga Fluconazole Capsule

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, ask your doctor or pharmacist for help.

-How much to use

Adults

The dose will depend on your infection and how you respond to this medicine. It usually ranges from 50mg to 400mg once daily.

Children

This medicine is not recommended to be used in children.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. They will tell you exactly how much to take.

Follow the instructions they give you. If you take the wrong dose, Pharmaniaga Fluconazole Capsule may not work as well and your problem may not improve.

-When to use 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 use it

Continue taking your medicine for as long as your doctor tells you.

The length of time you take this medicine will depend on the sort of infection you have.

Individuals 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 medicine because you are feeling better.

If you do not complete the full course prescribed by your doctor, the infection may not completely clear or your symptoms may return.

-If you forget to use it

Take your dose as soon as you remember, and continue to take it as you would normally.

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.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

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

-If you use too much (overdose)

Immediately telephone your doctor 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 Pharmaniaga Fluconazole Capsule. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

-Things you must do

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

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

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

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

-Things you must not do

Do not take Pharmaniaga Fluconazole Capsule 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 careful driving or operating machinery until you know how Pharmaniaga Fluconazole Capsule affects you.

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

PHARMANIAGA FLUCONAZOLE CAPSULE

Fluconazole (100mg, 150mg)

Be sure to follow your doctor's advice if regular checks on your liver are recommended.

In rare cases, Pharmaniaga Fluconazole may affect the liver and may need to be stopped.

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

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

Side effect

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Pharmaniaga Fluconazole Capsule.

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.

These are the most common side effects of the medicine:

- nausea
- abdominal pain
- diarrhea
- rash
- headache
- flatulence

Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers → Reporting Side Effects to

Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Pharmaniaga Fluconazole Capsule

-Storage

Keep out of the reach and sight of children.

Store below 30°C. Protect from light.

Do not use Pharmaniaga Fluconazole Capsule after the expiry date stated on the packaging. The expiry date refers to the last day of that month.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

What it looks like

Pharmaniaga Fluconazole Capsule 100mg:

White/dark blue hard gelatin size '2' capsule with 'Pharmaniaga' logo and '100' marking.

Pharmaniaga Fluconazole Capsule 150mg:

Light blue/light blue hard gelatin size '2' capsule with 'Pharmaniaga' logo and '150' marking.

Ingredients

Pharmaniaga Fluconazole Capsule 100mg:

Active ingredient(s): Fluconazole 100mg

Inactive ingredients:

Cornstarch, Tablettose 80, Sodium Starch Glycolate, Sodium Lauryl Sulphate, Colloidal Silicone Dioxide and Purified Talc.

Pharmaniaga Fluconazole Capsule 150mg:

Active ingredient(s): Fluconazole 150mg

Inactive ingredients:

Cornstarch, Tablettose 80, Sodium Starch Glycolate, Sodium Lauryl Sulphate, Colloidal Silicone Dioxide and Purified Talc.

-MAL Number(s)

Pharmaniaga Fluconazole Capsule 100mg:

MAL20031733AZ

Pharmaniaga Fluconazole Capsule 150mg:

MAL20031732AZ

Manufacturer

Pharmaniaga Manufacturing Berhad (198001006232), No. 11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Product Registration Holder

Pharmaniaga Manufacturing Berhad (198001006232), No. 11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

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