

FLUZOLE

fluconazole

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FLUZOLE capsules. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking FLUZOLE capsules against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What FLUZOLE is used for

FLUZOLE capsules are used to treat certain fungal and yeast infections.

This medicine belongs to a group of medicines called azole antibiotics.

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

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

Your doctor may have prescribed it for another reason.

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

This medicine is not addictive.

Before you take it

When you must not take it

Do not take FLUZOLE if you have an allergy to:

- any medicine containing fluconazole
- medicines related to fluconazole such as miconazole, ketoconazole or clotrimazole
- 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 or other parts of the body; rash, itching or hives on the skin.

FLUZOLE should not be given if you are taking cisapride (a medicine used to treat stomach problems).

Do not take this medicine if the expiry date printed on the packaging has passed 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 allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have any other health problems, including:

- liver problems
- heart problems
- kidney problems.

Tell your doctor if you are pregnant or if you plan to become pregnant or are breastfeeding.

Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell them before you start taking FLUZOLE.

Taking other medicines

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

Some medicines and fluconazole may interfere with each other.

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, erythromycin or voriconazole
- some drugs used for heart problems, such as quinidine or verapamil
- some drugs used in problems with the immune system, such as ciclosporin, tacrolimus, sirolimus, or tofacitinib
- cyclophosphamide, olaparib or ibrutinib (used to treat certain types of cancers)
- warfarin (used to stop blood clots)
- phenytoin (used to treat epilepsy)
- theophylline (used to treat asthma)

- some benzodiazepines such as midazolam
- hydrochlorothiazide (used for treating fluid problems)
- the contraceptive pill (birth control pill)
- carbamazepine (used in the treatment of epilepsy and bipolar disorder)
- 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
- tolvaptan (used to treat low levels of sodium in your blood or for kidney problems).

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

How to take FLUZOLE

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 on the box, ask your doctor or pharmacist for help.

How much to take

Adults

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

Children

FLUZOLE is not suitable for children weighing under 35 kg. The

dose for a child will depend on body weight and usually ranges from 3 mg to 12 mg per kg of body weight.

However, depending on how serious the infection is, and how you react to the medicine, your doctor may ask you to take a different dose.

How to take it

Swallow the capsules whole with water.

When to take it

Try to 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 to remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine until you finish the pack or until your doctor recommends.

The length of time you take this medicine 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 medicine 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 it

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

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

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre on 13 11 26 for advice, if you think that you or anyone else may have taken too much FLUZOLE.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking it

Things you must do

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

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

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

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

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

Things you must not do

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.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not use FLUZOLE to treat any other medical complaints unless your doctor tells you to.

Things to be careful of

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

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

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

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

Be careful when driving vehicles or operating machinery as occasional dizziness or seizures may occur.

Side effects

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

This medicine helps most people with fungal and yeast infections, but it may have a few unwanted effects in some people. 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.

Ask your doctor or pharmacist to answer any questions you may have.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

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

- acne.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

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

- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives
- flaking of the skin
- fainting, seizures or fits
- 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
- fast or irregular heart beat
- increased sweating.

These side effects are usually rare but can be serious and need urgent medical attention.

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

This is not a complete list of all possible side effects. Others may also occur in some people and there may be some side effects not yet known.

After using FLUZOLE

Storage

Keep your capsules in the blister pack until it is time to take them.

If you take the capsules out of the pack, they may not keep well.

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

Do not store FLUZOLE 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 it 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

FLUZOLE 200 – violet and white opaque capsules.

Each pack contains 28 capsules.

Ingredients

The active ingredient in FLUZOLE is fluconazole.

- each FLUZOLE 200 contains 200 mg of fluconazole.

The capsules also contain:

- 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) (50 mg and 200 mg capsule shells only).

This medicine contains sugars (as lactose) and may contain trace amounts of phenylalanine and sulfites.

The capsules do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia

Australian registration numbers:

FLUZOLE 50 – AUST R 120775 *

FLUZOLE 50 – AUST R 120776 *

FLUZOLE 200 - AUST R 120778

*Not marketed in Australia

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