

NEW ZEALAND CONSUMER MEDICINE INFORMATION

FLUCONAZOLE

Fluconazole 50 mg, 150 mg and 200 mg

What is in this leaflet

This leaflet answers some common questions about Fluconazole 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 using Fluconazole capsules against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine. You may need to read it again.

What Fluconazole is used for and how it works

Your Fluconazole capsules contain fluconazole. It belongs to a group of medicines known as antifungals.

Fluconazole is used to treat certain fungal and yeast infections. 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.

Fluconazole is only available with a doctor's prescription.

Before you take Fluconazole

When you must not take it

Do not take Fluconazole if you have an allergy to the following:

- 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.

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

- **cisapride** (a medicine used to treat stomach problems)
- **astemizole** (an antihistamine used to treat allergies)
- **erythromycin** (an antibiotic used in the treatment of infections)
- **pimozide** (an antipsychotic medicine)
- **quinidine** (a medicine used to treat an irregular heartbeat)
- **terfenadine** (an antihistamine used to treat allergies) if you are taking more than 400 mg fluconazole a day.

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 allergies to any other medicines, foods, preservatives or dyes. Fluconazole capsules contain lactose and should be avoided if you have an intolerance to lactose or a deficiency that affects your ability to metabolise or absorb lactose.

Tell your doctor if you have or have had any of the following medical conditions:

- any liver problems
- any heart problems
- any kidney problems.

You should not take Fluconazole if you are pregnant, think you may be pregnant, are trying to become pregnant or breast-feeding, unless your doctor has told you so.

Fluconazole taken during the first trimester of pregnancy may increase the risk of miscarriage. Fluconazole taken at low doses during the first trimester may slightly increase the risk of a baby being born with birth defects affecting the bones and/or muscles.

If you have not told your doctor about any of the above, tell them before you take Fluconazole.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from

your pharmacy, supermarket or health food shop.

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

- some medicines for diabetes such as chlorpropamide, glipizide, tolbutamide or glibenclamide
- some antibiotics and antiviral drugs such as rifampicin, rifabutin, zidovudine, saquinavir, voriconazole and amphotericin B
- some medicines used in problems with the immune system, such as ciclosporin, tacrolimus or sirolimus.
- medicines used to stop blood clots such as warfarin or indanedione
- some medicines used to treat epilepsy such as phenytoin or carbamazepine
- theophylline (used to treat asthma)
- some benzodiazepines such as midazolam or triazolam
- hydrochlorothiazide (used for treating fluid problems)
- alfentanil (used in anaesthesia)
- lemborexant (used to treat insomnia)
- ivacaftor (used to manage cystic fibrosis)
- lurasidone (used to manage schizophrenia)
- ibrutinib (used in cancer treatment)
- tolvaptan (used to treat low levels of sodium in your blood)
- amitriptyline and nortriptyline (used in the treatment of depression)
- some medicines used to treat high blood pressure and angina such as nifedipine, isradipine, amlodipine, verapamil, felodipine and losartan
- amiodarone (used to treat irregular heartbeat)
- celecoxib (used in the treatment of arthritic conditions)
- cyclophosphamide (used in the treatment of some cancers)

- fentanyl (an analgesic used in the treatment of severe chronic pain)
- halofantrine (used to treat malaria)
- some medicines used to treat high cholesterol such as atorvastatin, simvastatin and fluvastatin
- methadone (used in the treatment of dependence on opioid drugs)
- NSAIDs (non-steroidal anti-inflammatory drugs) such as naproxen, lornoxicam, meloxicam and diclofenac
- olaparib (used in the treatment of breast cancer)
- prednisone (used as an anti-inflammatory and also in some immune system disorders)
- tofacitinib (used in treatment of rheumatoid arthritis)
- vinca alkaloids, such as vincristine and vinblastine (used in the treatment of cancers)
- vitamin A and derivatives.

These medicines 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.

This medicine may decrease the effectiveness of some birth control pills. Talk to your pharmacist or doctor about the need for an additional method of contraception while taking Fluconazole.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Fluconazole.

How to take Fluconazole

Follow all directions given to you by your doctor and 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 Fluconazole. It usually ranges from 50 mg to 200 mg once daily.

Children

The dose for a child will depend on body weight and usually ranges from 3 mg to 12 mg per kilogram of body weight. In very young children (below 4 weeks of age), Fluconazole is usually given every second or third day.

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 a glass of water.

When to take 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 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 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 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 your capsules as you would normally.

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

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

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

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) 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 Fluconazole. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking Fluconazole

Things you must do

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

If you are a woman of child-bearing age, you should avoid becoming pregnant while taking Fluconazole. Tell your doctor immediately if you do become pregnant while taking Fluconazole.

If you suffer from HIV or have a weakened immune system and develop a rash while taking Fluconazole, tell your doctor immediately. If this rash worsens, Fluconazole may need to be stopped.

If you are about to be started on any new medicine, remind your doctor

or pharmacist that you are taking Fluconazole.

Tell all doctors, dentists and pharmacists who treat you that you are taking Fluconazole.

Things you must not do

Do not stop taking Fluconazole 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 Fluconazole to anyone else, even if they have the same condition as you.

Do not use Fluconazole 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, Fluconazole may affect the liver and may need to be stopped.

Be careful driving or operating machinery as dizziness or seizures have occurred in isolated cases when taking Fluconazole

Side effects

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

All medicines can have some unwanted effects. Sometimes they are serious, most of the time they are not. You may need medical treatment 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.

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

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

These are some of the more common side effects of Fluconazole. They are usually mild and short-lived.

Other less common side effects are:

- 'pins and needles' feeling in hands or feet
- altered taste
- tremors
- skin rash, itching, dry skin, or hives
- dizziness
- hair loss
- generally feeling unwell, tiredness, chills, pain and thirst
- back pain, kidney pain and aching muscles
- loss of appetite
- altered sight or hearing
- trouble sleeping or sleepiness
- irregular, heavy or painful menstrual periods
- increased sweating
- hot flushes
- blurred or abnormal vision
- constipation
- fatigue
- muscle cramps.

Tell your doctor as immediately 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
- fainting, seizures or fits
- sudden or severe blisters and bleeding in lips, eyes, mouth, nose and genitals
- flaking of the skin
- 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
- dark urine and light-coloured bowel movements.

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.

Other side effects not listed above may also occur in some people. Some of these side effects, for example, changes in liver function, can only be found when your doctor does tests from time to time to check your progress.

After taking Fluconazole

Storage

Keep your capsules in the 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 Fluconazole 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 that are left over.

Product description

What it looks like

Fluconazole capsules come in three strengths:

- Fluconazole 50 mg – hard gelatin, opaque white/dark blue capsule marked “FC 50” and “G” in black
- Fluconazole 150 mg – hard gelatin, opaque white capsule marked “FC 150” and “G” in black
- Fluconazole 200 mg – hard gelatin, opaque white/blue capsule marked “FC 200” and “G” in black.

Ingredients

Active ingredient(s):

The active ingredient in Fluconazole capsules is fluconazole.

- Each Fluconazole 50 mg capsule contains 50 mg of fluconazole
- Each Fluconazole 150 mg capsule contains 150 mg of fluconazole
- Each Fluconazole 200 mg capsule contains 200 mg of fluconazole

Inactive ingredient(s):

Fluconazole capsules also contain:

Capsule Fill:

- lactose
- maize starch
- sodium lauryl sulphate
- colloidal hydrated silica
- magnesium stearate

Capsule Shell:

- gelatin
- titanium dioxide (E171)
- patent blue V (E131) (50 mg and 200 mg capsules only)
- erythrosine (E127) (50 mg capsules only)

Printing Ink:

- shellac
- dehydrated alcohol
- isopropyl alcohol
- butyl alcohol
- propylene glycol
- ammonia solution
- potassium hydroxide
- black iron oxide (E172).

Fluconazole capsules contains sulfites and sugars as lactose.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Arrotex Pharmaceuticals
(NZ)Limited
C/o Quigg Partners
Level 7, The Bayleys Building
36 Brandon Street
Wellington 6011, New Zealand

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