

NEW ZEALAND CONSUMER MEDICINE INFORMATION

FLUCAZOLE®

Fluconazole capsules 150 mg

What is in this leaflet

Please read this leaflet carefully before you start taking Flucazole.

This leaflet answers some common questions about Flucazole.

It does not contain all the information available on this medicine. It does not take the place of talking to your pharmacist or doctor.

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

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

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

What Flucazole is taken for and how it works

Your Flucazole capsule contains fluconazole. It belongs to a group of medicines known as antifungals.

Flucazole is used to treat vaginal thrush infections. It works by preventing the growth of fungal and yeast organisms.

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.

Flucazole is available over the counter at a pharmacy or with a doctor's prescription.

Before you take Flucazole

When you must not take it

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

- any medicine containing fluconazole
- medicines related to fluconazole such as miconazole, ketoconazole, itraconazole, clotrimazole or voriconazole
- 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).

Do not give Flucazole to a child under the age of 18 years unless prescribed by a doctor.

Safety and effectiveness in children younger than 18 years have not been established.

Do not take Flucazole if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in Flucazole passes into breast milk and there is a possibility that your baby may be affected.

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.

Talk to your pharmacist or doctor if you are not sure whether you should take this medicine.

Before you take it

Tell your pharmacist or doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

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

Tell your doctor if you are lactose intolerant. This medicine contains lactose.

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

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 Flucazole may interfere with each other. These include:

- cisapride (used to treat stomach problems)
- pimozone (an antipsychotic medicine)
- some medicines used to treat allergies such as terfenadine or astemizole
- some medicines for diabetes such as chlorpropamide, glipizide, tolbutamide, glibenclamide, gliclazide, glimepiride pioglitazone or rosiglitazone
- some antibiotic, antiviral and antifungal medicines such as rifampicin, rifabutin, zidovudine, saquinavir, voriconazole, amphotericin B and erythromycin
- some medicines used in problems with the immune system, such as ciclosporin, tacrolimus or sirolimus
- warfarin or other blood thinners (used to stop blood clots)
- 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)
- abrocitinib (used to manage eczema)
- alfentanil (used in anaesthesia)
- amitriptyline and nortriptyline (used in the treatment of depression)
- some medicines used to treat high blood pressure and angina such as nifedipine, isradipine, losartan, verapamil, amlodipine and felodipine
- amiodarone or quinidine (used to treat irregular heart beats)
- 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 ibuprofen, flurbiprofen, naproxen, lornoxicam, meloxicam and diclofenac
- prednisone (used as an anti-inflammatory and also in some immune system disorders)
- tofacitinib (used in the treatment of rheumatoid arthritis)
- vinca alkaloids, such as vincristine and vinblastine (used in the treatment of cancers)
- Vitamin A and its derivatives
- tolvaptan (used to treat kidney disease)
- ibrutinib (used to treat blood cancers)
- ivacaftor (used to manage cystic fibrosis)
- lemborexant (used to treat insomnia)
- lurasidone (used to manage schizophrenia)
- medicines that protect the stomach lining (increase gastric pH) such as cimetidine, antacids containing aluminium or magnesium.

These medicines may be affected by Flucazole or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take Flucazole

Directions for use

Take ONE capsule as a single dose.

Swallow whole with a glass of water.

Your Flucazole capsule can be taken any time of the day.

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

Follow all directions given to you by your pharmacist or doctor and read the instructions on the carton.

Your Flucazole capsule is a single dose treatment for vaginal thrush infections which you take by mouth.

While you are taking Flucazole

Things you must do

Tell your pharmacist or 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 Flucazole.

Tell your doctor immediately if you become pregnant in the same month as taking Flucazole.

If you are about to be started on any new medicine, remind your pharmacist or doctor that you have recently taken Flucazole.

Tell all doctors, dentists and pharmacists who treat you that you have recently taken Flucazole.

If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.

Things you must not do

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

Do not use Flucazole to treat any other medical complaints.

Things to be careful of

Be careful driving or operating machinery until you know how Flucazole affects you. This medicine may cause dizziness, vertigo, tiredness, vision problems and seizures in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Be careful when drinking alcohol while you are taking this medicine. If you drink alcohol, dizziness vertigo, tiredness, vision problems and seizures may be worse.

In case of overdose

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken Flucazole by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of Flucazole with you if you can.

Keep telephone numbers for these places handy.

Side effects

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are taking Flucazole. This medicine helps most people with vaginal thrush infection, but it may have unwanted side effects in a few people.

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.

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

- nausea or feeling sick
- headache
- stomach pain
- indigestion
- diarrhoea
- constipation
- vomiting
- flatulence (passing gas)
- dry mouth
- changes in appetite
- thirst
- changes in sleep patterns

- nervousness
- dizziness or vertigo
- changes in taste
- hair loss
- dry skin
- increased sweating
- hot flushes
- back pain
- changes in sex drive
- fatigue or muscle weakness
- passing abnormally large amounts of urine
- changes in body odour
- tingling or prickling, “pins-and-needles” sensation
- excessive restlessness
- abnormal pain
- cold sores around the mouth or genitals
- pelvic pain
- stiff muscles

These are the more common side effects of Flucazole. They are usually mild.

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

- signs of frequent or worrying infections such as fever, severe chills, sore throat or mouth ulcers
- tremor
- changes in menstrual cycles (irregular, painful or heavy periods)
- yellowish vaginal discharge
- abnormal vision
- feeling of cold with shivering accompanied by a fever
- kidney pain

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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, peeling or blistering of the skin
- fainting, seizures or fits
- 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
- fast or irregular heart beat.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your pharmacist or doctor.

Some of these side effects (for example, changes in cholesterol level or potassium level in your blood) can only be found when your doctor does tests from time to time to check your progress.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Storage

Keep your Flucazole capsule in the blister pack until it is time to take it.

Store your Flucazole capsule below 25°C. Keep out of reach of children. Avoid exposure to heat and moisture.

Do not store Flucazole, 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 you do not take your Flucazole capsule or it has passed the expiry date, ask your pharmacist what to do with it.

Product description

Flucazole comes in a pack containing one capsule.

What it looks like

Gelatin capsule with white opaque body and white opaque cap. The body has "FC 150" and the cap has "G" printed in black. The capsule contains white to off-white powder.

Ingredients

Active ingredient:

Flucazole contains 150 mg of fluconazole as the active ingredient.

Inactive ingredients:

Flucazole also contains:

- lactose,
- maize starch,
- sodium lauryl sulphate,
- colloidal hydrated silica,
- magnesium stearate,
- gelatin,
- titanium dioxide (E171)
- Tekprint Ink SW-9008 and SW-9009.

Flucazole contains sulfites and sugars as lactose.

If you want to know more

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

Who supplies this medicine

Flucazole is supplied in New Zealand by:

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

Date of Preparation

18 December 2024 (Based on data sheet dated 12 December 2024)