

OZOLE

fluconazole

50 mg and 200 mg capsules

What is in this leaflet

Please read this leaflet carefully before you start taking Ozole.

This leaflet answers some common questions about Ozole. 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 Ozole 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 Ozole is used for

Ozole is used to treat some fungal and yeast infections and may also be used to stop you from getting a fungal infection.

Ozole belongs to a group of medicines called azole antifungals. It works by stopping the growth of the fungal and yeast organisms causing your infection.

Your doctor may have prescribed Ozole for another reason.

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

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

Before you take Ozole

When you must not take it

Do not take Ozole if you have an allergy to:

- any medicine containing fluconazole, or any other medicine that is related to fluconazole, e.g. miconazole, ketoconazole or clotrimazole
- any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- difficulty in breathing or wheezing
- shortness of breath
- swelling of the face, tongue, lips, or other parts of the body
- hives on the skin, rash, or itching

Do not take Ozole if you have ever developed a severe skin rash or skin peeling, blistering and/or mouth sores after taking fluconazole. Serious skin reactions including drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with fluconazole treatment. **Stop taking Diflucan and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions.**

Do not take Ozole if you are taking:

- terfenadine (antihistamine medicines for allergies)
- cisapride (used for stomach upsets)
- astemizole (antihistamine medicines for allergies)
- erythromycin (an antibiotic for treating infections)
- pimozide (used for treating mental illness)
- quinidine (used for treating heart arrhythmia)

Do not take it after the expiry date (EXP) printed on the back. If you take it after the expiry date has passed, it may not work as well.

Do not take it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using Ozole, talk to your doctor.

Before you start to take it

Tell your doctor if:

- 1. you have allergies to:**
 - Any other medicines
 - Any other substances, such as foods, preservatives or dyes
- 2. you have, or have had, the following medical conditions:**
 - problems with your liver
 - problems with your heart, including heart rhythm problems
 - severe kidney problems
 - severe skin reactions (itching, reddening of the skin or difficulty in breathing)
 - you have abnormal levels of potassium, calcium or magnesium in your blood
 - you have AIDS
- 3. 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 using Ozole.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should also tell any health professional who is prescribing a new medication for you that you are taking Ozole.

Some medicines may interfere with Ozole. These include:

- some medicines used to treat symptoms of allergy.

- glibenclamide, glipizide, and tolbutamide (used to treat diabetes).
- antibiotics, antivirals and antifungals medicines. Examples are: rifabutin, rifampicin, amphotericin B, azithromycin, erythromycin, saquinavir, zidovudine, voriconazole.
- ciclosporin, tacrolimus, tofacitinib or sirolimus (used to prevent transplant reject)
- medicines that thin the blood to prevent blood clots (warfarin or similar medicines)
- phenytoin (used for treating fits).
- carbamazepine (used for treating fits and bipolar disorder)
- theophylline (used to control asthma symptoms).
- benzodiazepines, for example midazolam and triazolam used to help you sleep or for anxiety.
- hydrochlorothiazide used to treat fluid problems.
- tolvaptan (used to treat low levels of sodium in your blood or for kidney problems)
- oral contraceptives.
- nifedipine, isradipine, amlodipine, verapamil, felodipine and losartan (for hypertension- high blood pressure).
- amitriptyline and nortriptyline (used as antidepressants).
- naproxen, diclofenac, lornoxicam, meloxicam and celecoxib (non-steroidal anti-inflammatory medicines).
- opioid pain killers such as methadone, alfentanil and fentanyl.
- amiodarone, quinidine or verapamil (used for heart problems).
- cyclophosphamide, vinca alkaloids (vincristine, vinblastine or similar medicines), ibrutinib and olaparib (used to treat certain types of cancer).
- atorvastatin, simvastatin and fluvastatin (used for reducing high cholesterol levels)
- halofantrine (used to treat malaria).
- cimetidine (medicine used for gastrointestinal problems).
- vitamin A (nutritional supplement)
- prednisone (steroid)

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

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

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

How to take Ozole

How much to take

Follow all directions given to you by your doctor or pharmacist carefully. Your doctor may have prescribed a different dose.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

Adults

The dose is usually from 50 mg to 400 mg once daily but does depend on your infection and how it responds to Ozole.

Children

The dose for a child is determined by their body weight. It usually ranges from 3 mg to 12 mg per kilogram. In very young children (below 4 weeks of age), Ozole is usually given every second or third day.

However, your doctor may prescribe a different dose depending on your reaction to the medicine, and/or seriousness of the infection.

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. This medicine can be taken before or after food.

How long to take it

Continue taking Ozole for as long as your doctor has advised you to, or until you finish the pack.

The length of time you take Ozole 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 Ozole 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.

While you are taking Ozole

Things you must do

If your symptoms do not begin to improve within a few days, or they become worse, tell your doctor as alternative antifungal therapy may be needed.

You should not take Ozole if you are pregnant, think you may be pregnant, are trying to become pregnant or breastfeeding 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 are about to be started on any new medicine, remind your doctor or pharmacist that you are taking Ozole.

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

Things you must not do

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

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

Things to be careful of

Your doctor may recommend that you have regular liver checks. In rare cases, Ozole may affect your liver and treatment may need to be stopped.

If you develop a rash while taking Ozole, tell your doctor immediately since Ozole may need to be stopped. This is especially important if you suffer either from HIV or have a weakened immune system.

Be careful driving or operating machinery until you know how Ozole affects you. When driving vehicles or using machines, it should be taken into account that occasionally dizziness or fits may occur.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Ozole.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

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

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.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects.

Do not be alarmed by this list of possible adverse 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, feeling sick or 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. Do not be alarmed by this list. You may not experience any of them.

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

- 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-including widespread blistering rash and skin peeling, severe skin reactions.
- fainting, seizures or fits.
- flaking of the skin.

- fast or irregular heart beats
- increased sweating
- 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.

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 taking Ozole

Storage

Keep your medicines in its original pack until it is time to take them. If you take the tablets out of the pack they may not keep well.

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

Do not store Ozole in the bathroom or near a sink. Do not leave it in the car or on a windowsill. 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 they have passed their expiry date, ask your pharmacist what to do with any unused medicine. **Return any unused medicine to your pharmacist.**

Product description

What it looks like

Ozole 50 mg – blue cap/white body printed Ranbaxy on both cap and body.

Ozole 200 mg – purple cap and white body printed Ranbaxy on both cap and body.

All strengths come in a box of 28 or 30 capsules. Not all pack sizes marketed.

Ingredients

Ozole contains 50 mg or 200 mg of fluconazole as the active ingredient.

Inactive ingredients:

- lactose monohydrate, maize starch, sodium lauryl sulphate, colloidal anhydrous silica, and magnesium stearate.
- In addition, the capsules shells contain: gelatin, patent blue(E133) and titanium dioxide (E171) for the 50 mg capsules and gelatin, patent blue (E133), erythrosine (E127) and titanium dioxide (E171) for the 200 mg capsules. The black colour in the printing ink is black iron oxide (E172).

Sponsor details

Ozole is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd

P O Box 45 027

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New Zealand

Phone: (09) 835 0660

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08 June 2022

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