

OZOLE

Fluconazole Capsules

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about OZOLE (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 you taking OZOLE against the benefits it is expected to have for you.

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

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

What OZOLE is used for

OZOLE contains fluconazole. Fluconazole belongs to a group of medicines called azole antibiotics, used to treat fungal infections. The most common cause of such infections is a fungus called Candida.

Your doctor would have prescribed OZOLE for one or more of the following:

- Treatment of fungal infections of the mouth (oral thrush), throat, or food pipe by Candida in patients who have suppressed immunity
- Treatment of fungal infections of the skin (such as those involving groin, area between the toes) not responding to local antifungal application therapy
- Treatment of serious internal fungal infections caused by Candida (such as those involving blood, urinary tract, lungs or other body organs) in patients who are unable to tolerate intravenous antifungal therapy with amphotericin B
- Treatment of fungal infections of the brain caused by a fungus Cryptococcus (a condition called cryptococcal meningitis) in patients not tolerating intravenous antifungal therapy with amphotericin B
- Treatment of vaginal fungal infections (vaginal thrush) when local antifungal application therapy has failed
- To prevent fungal infections (if your immune system is not working properly)
- To prevent cryptococcal meningitis infections in patients with AIDS and/or HIV infection

Your doctor may prescribe OZOLE for another reason. Ask your doctor if you have any questions about why OZOLE has been prescribed for you.

There is no evidence that OZOLE capsules are addictive.

OZOLE is not expected to affect your ability to drive a car or operate machinery.

Before you take OZOLE

When you must not take it

Do not take OZOLE if you are allergic to fluconazole or antifungals 'azoles' or to any of the inactive ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include skin rash, itching, shortness of breath, swelling of the tongue or face.

Do not take OZOLE if you are taking cisapride (a medicine used to treat certain digestive problems), astemizole (used in the treatment of allergy symptoms), erythromycin (an antibiotic used to treat bacterial infections), pimozide (an antipsychotic medication), quinidine (used to treat abnormal heart rhythms) and terfenadine (used to treat allergic conditions).

Do not take OZOLE after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well or may cause harm. Do not take OZOLE if the capsules do not look quite right.

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

Before you start to take it

Tell your doctor if you have any allergies to:

- any other medicines containing 'azole', or any antifungals
- any other substances, such as foods, preservatives or dyes

Tell your doctor if you are pregnant or breast-feeding.

Your baby may absorb this medicine in the womb or from breast milk and therefore there is a possibility of harm to the baby.

Tell your doctor if you intend to become pregnant.

Like many other medicines, OZOLE may affect your developing baby if you take it during pregnancy. If it is necessary for you to take OZOLE, your doctor can help you decide whether or not to take it during pregnancy.

Tell your doctor if you are breast-feeding or planning to breast-feed.

Your doctor will discuss the possible risks and benefits of using OZOLE during breast-feeding.

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

- You are pregnant, or planning to become pregnant, or are breast-feeding
- You have had problems with your liver and/or kidneys. Your doctor may reduce the dose of OZOLE.
- You are an elderly person above 65 years of age
- You have problems with your heart
- You have been diagnosed to have AIDS
- You have had any altered blood electrolyte levels
- You have or have had any chronic illness
- You have been diagnosed to have cancer

Your medicine also contains small amounts of an inactive ingredient called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking OZOLE.

Tell your doctor if you plan to have blood/urine test.

If you need a laboratory investigation such as blood test or urine test, do inform your doctor about the medicine you are taking.

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

Taking other medicines

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

Some medicines may interfere with the absorption or action of fluconazole.

These include:

- Blood thinning medicines (warfarin or coumarin drugs)
- Sugar diabetes medicines (such as chlorpropamide, glibenclamide, glipizide or tolbutamide)
- Water tablets (diuretics, e.g., furosemide, hydrochlorothiazide)
- Benzodiazepines (such as midazolam used as tranquillizers)
- Phenytoin, valproic acid (used to treat convulsions)
- Some drugs used for heart problems, such as quinidine or verapamil
- Some antibiotics, antiviral and antifungal drugs such as rifampicin, rifabutin, zidovudine, amphotericin B, erythromycin, saquinavir or voriconazole
- Some drugs used in problems with the immune system, such as cyclosporin, tacrolimus, sirolimus or tofacitinib
- Theophylline (medicines used to treat asthma)
- Anti allergic medicine (terfenadine)
- Cimetidine (a medicine for a type of digestive disorder)
- Hormonal contraceptive pills ("oral pills")
- Isoniazid (antibacterial agent used to treat an infection called tuberculosis)
- Amiodarone (used to treat and prevent irregular heartbeats)
- Carbamazepine (used for treatment of epilepsy and bipolar disorder)
- Calcium channel blockers (used as anti-hypertensive drugs)
- NSAIDs such as naproxen, diclofenac and celecoxib
- Cyclophosphamide (used as to treat certain types of cancers)
- Opioid pain killers such as alfentanil, fentanyl and methadone
- Halofantrine (used to treat malaria)
- HMG-CoA reductase inhibitors (statins)
- Losartan (used to treat high blood pressure)
- Sulfonylureas (antidiabetic drugs)
- Vinca Alkaloids (for cancer treatment)
- Vitamin A

Antidepressants such as amitriptyline and nortriptyline. These medicines may be affected by fluconazole, or may affect how well it works. You may need to use different

amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist will be able to tell you what to do when taking/being given OZOLE capsules with other medicines.

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

How OZOLE is given

How much to take

Your doctor will tell you how many capsules you will need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

Take your medicine as instructed by your doctor. Do not take more than the doctor told you to. Check the label carefully for how much to take and how often to take. Your pharmacist or doctor can help if you are not sure.

How to take it

Swallow the capsule whole with a glass of water. OZOLE capsules may be taken with or without food.

Adults

The dose will depend on your infection and how you respond to OZOLE. The usual recommended dose in adults ranges from 50 to 400 mg per day. For treatment of meningitis and prevention of relapse, your doctor may start you on a higher dose of 400 mg on the first day followed by a dose of 200 mg from the second day onwards. Depending on the type, severity of the infection, and response to treatment the duration of treatment may vary.

For treatment of infections caused by *Candida* the usual recommended dose in adults varies from 50 to 200 mg per day depending on the type and severity of infection.

Your daily doses would be different if you are an elderly person, or you have kidney problems, or you are on dialysis.

When to take it

Take your OZOLE capsules at about the same time every day. Taking your capsules at the same time will have the best effect. It will also help you to remember when to take the capsules.

How long to take it

Continue taking OZOLE capsules until your doctor tells you to stop.

OZOLE helps cure your infection. Therefore you must take your medicine every day, until your doctor tells you to stop.

To help stop your infections from coming back, you may need to take your medicines for longer.

Do not stop taking OZOLE capsules because you begin to feel better.

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, some of the fungus causing your infection may persist.

Do not let yourself run out of medicine over the weekend or on holidays.

Stopping OZOLE without doctor's advice may make your infection worse. Your doctor will decide when you should stop taking it.

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 double a dose to make up for the dose you have missed.

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 take too much (Overdose)

Immediately telephone your doctor, or the Poisons Information Centre on 131126, or go to Emergency department at your nearest hospital, if you think that you or anyone else has taken too much of OZOLE capsules. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep this telephone number handy.

While you are using OZOLE

Things you must remember

Take OZOLE capsules exactly as your doctor tells you to.

Try not to miss any doses and take the medicine even if you feel well.

Visit your doctor regularly for check-ups.

Tell all doctors, dentists and pharmacists who are treating you that you are taking OZOLE capsules.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking OZOLE capsules.

Tell your doctor if you are to undergo any blood or urine test.

If you become pregnant while taking OZOLE capsules, tell your doctor immediately.

Things you must not do

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

Do not use OZOLE capsules to treat any other complaints unless your doctor tells you to.

Do not stop taking OZOLE capsules, or lower the dose, without first checking with your doctor.

Things to be careful of

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

In rare cases, OZOLE capsules may affect your liver and may need to be stopped.

If you have HIV or are have a suppressed immune system and you develop a rash while taking OZOLE, tell your doctor immediately.

If you have a pre-existing heart disease or any abnormalities of rhythm then you should follow up with your doctor regularly.

Side effects

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

Ask your doctor or pharmacist any questions you may have.

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

- **Feeling sick (nausea), being sick (vomiting), constipation, diarrhoea (loose stools), pain in the belly, indigestion, wind (flatulence), decreased appetite, dryness of mouth, altered taste, increased thirst, ulceration in the mouth**
- Headache, tiredness, generalised weakness, aches and pain, chills, shivers, dizziness, sleep disturbances, hot flushes, flushing
- Stiffness of body, increased muscle tone, nervousness, pins and needles sensation, numbness
- Visual disturbances
- Back ache
- Increased urination, pain in the loin
- Vaginal discharge and itching
- Painful menstruation, heavy cycles, bleeding in between periods (spotting), pain in the lower belly in females
- Sexual dysfunction in females
- Abnormal skin odour and itching
- Increased blood pressure
- Difficulty in breathing
- Diminished hearing

These are the more common side effects of fluconazole. These side effects are usually mild and occur at the start of treatment.

Tell your doctor immediately if you notice any of the following

- Unusual bleeding or increased tendency to bleed, persistent sore throat and frequent infections, and/or anaemia
- Yellowing of skin and whites of eyes with decreased appetite
- Loss of hair
- Convulsions
- Cardiomyopathy (a disease of the heart muscle) which may manifest as shortness of breath, swelling of ankles
- Irregular heart beat

Tell your doctor immediately or go to Emergency department at your nearest hospital if you notice any of the following:

- Symptoms of an allergic reaction which may include rashes, hives, itching, chest constriction, shortness of breath or swelling of face, lips, tongue, hands/feet, fainting, dizziness
- Severe skin reactions with blisters, sores or ulceration
- Lesions in the skin with blisters and burning sensation (caused by a viral infection called herpes simplex)

These are very serious side effects. You may need urgent medical attention or hospitalisation. All these side effects are very rare.

Changes in the laboratory blood tests:

- Abnormal liver function tests
- Increase in cholesterol and triglyceride levels
- Altered levels of electrolytes sodium and potassium
- Decrease in level of calcium

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

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

This leaflet was prepared in November 2018.

After using it

Storage

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

If you take the capsules out of the box or the blister pack they may not keep well.

Keep your OZOLE in a cool, dry place where it stays below 25°C.

Do not store it, or any other medicine, in the bathroom or near a sink. Do not leave it in the car on hot days. Heat and dampness can destroy some medicines.

Keep this medicine where young children cannot reach it.

Disposal

If your doctor tells you to stop taking OZOLE capsules or you find that they have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

OZOLE 50 mg

are blue/white hard gelatin, self-locked capsules of size '4' imprinted with 'RANBAXY' in black edible ink on both cap and body containing white to off-white powder. Available in a pack of 28 capsules.

OZOLE 100 mg

are blue/white hard gelatin, self-locked capsules of size '2' imprinted with 'RANBAXY' in black edible ink on both cap and body containing white to off-white powder. Available in a pack of 28 capsules.

OZOLE 200 mg

are purple/white hard gelatin, self-locked capsules of size '0' imprinted with 'RANBAXY' in black edible ink on both cap and body containing white to off-white powder. Available in a pack of 28 capsules.

Ingredients

Active ingredient:

OZOLE 50 mg Capsule - Contains 50 mg of fluconazole

OZOLE 100 mg Capsule - Contains 100 mg of fluconazole

OZOLE 200 mg Capsule - Contains 200 mg of fluconazole

Inactive ingredients:

Lactose monohydrate, maize starch, colloidal anhydrous silica, magnesium stearate and sodium lauryl sulfate and Tek Print SW-9008 Black Ink.

Capsule shell composition:

Patent blue, titanium dioxide, gelatin, erythrosine (100 mg & 200 mg only).

Australian Registration Numbers

OZOLE 50 mg: AUST R 122901

OZOLE 100 mg: AUST R 122903

OZOLE 200 mg: AUST R 122909

Sponsor

OZOLE capsules are supplied in Australia by:

Sun Pharma ANZ Pty Ltd
Suite 2.02, Level 2
12 Waterloo Road
Macquarie Park NSW 2113