OZOLE

Fluconazole Capsules

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using OZOLE?

OZOLE contains the active ingredient fluconazole. OZOLE capsules are used to treat certain fungal and yeast infections.

For more information, see Section 1. Why am I using OZOLE? in the full CMI.

2. What should I know before I use OZOLE?

Do not start treatment if you are allergic to any medicine containing fluconazole, any of the ingredients listed at the end of this CMI, or any other similar medicines such as miconazole, ketoconazole or clotrimazole. Tell your doctor if you have had any allergic reactions to any antifungal or any food, preservatives or dyes or any other medicines, if you are pregnant, plan to become pregnant or are breastfeeding. You must not be given OZOLE if you are taking certain medicines.

For more information, see Section 2. What should I know before I use OZOLE? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OZOLE and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use OZOLE?

OZOLE is available as capsules which are swallowed whole with water. Your doctor will decide how much OZOLE will be given to you each day and for how long. It will depend on your condition and other factors.

More instructions can be found in Section 4. How do I use OZOLE? in the full CMI.

5. What should I know while using OZOLE?

Things you should do	• Tell the doctor if you have any medical conditions, are on any medicines, or if you are pregnant, plan to become pregnant or are breastfeeding. • For more information on "Things you should do" can be found in Section 6 in the full CMI
Things you should not do	• Do not start treatment if you have ever had an allergic reaction to any medicine containing fluconazole, any of the ingredients listed at the end of this CMI, or any other similar medicines such as miconazole, ketoconazole or clotrimazole. • Do not stop taking OZOLE or lower the dosage without checking with your doctor. • Do not give your medicine 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.
Looking after your medicine	• Keep your medicine in a cool dry place where the temperature stays below 25°C. • Store it in a cool dry place away from moisture, heat, or sunlight; for example, do not store it in the bathroom or near a sink, or in the car or on window sills. • Do not use this medicine after expiry date

For more information, see Section 5. What should I know while using OZOLE? in the full CMI.

6. Are there any side effects?

OZOLE is generally well tolerated. Side effects may include nausea, vomiting, abdominal pain, diarrhoea, headache, skin rash or redness and easy bruising of the skin, seizures, signs of frequent or worrying infections such as fever, severe chills, sore throat, or mouth ulcers, or change in liver function.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

OZOLE

Active ingredient(s): *Fluconazole*

Consumer Medicine Information (CMI)

This leaflet provides important information about using OZOLE. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using OZOLE.**

Where to find information in this leaflet:

1. Why am I using OZOLE?
2. What should I know before I use OZOLE?
3. What if I am taking other medicines?
4. How do I use OZOLE?
5. What should I know while using OZOLE?
6. Are there any side effects?
7. Product details

1. Why am I using OZOLE?

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

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

Your doctor may have prescribed this medicine for another reason.

There is no evidence that OZOLE capsules are addictive.

This medicine is not suitable for children weighing less than 35 kg.

2. What should I know before I use OZOLE?

Warnings

Do not use OZOLE if:

- you are allergic to fluconazole or antifungals 'azoles' or any of the ingredients listed at the end of this leaflet, or related to any medicines such as miconazole, ketoconazole or clotrimazole
- Symptoms of an allergic reaction may include skin rash, itching or hive; shortness of breath, wheezing or difficulty breathing; swelling of the face, lip, tongue or other parts of the body.

Do not use OZOLE if you are taking any of the following medicines:

- terfenadine or astemizole (a medicine used to treat allergies).
- cisapride (a medicine used to treat digestive problems)
- erythromycin (a medicine used to treat infections)
- primozide (a medicine used to treat mental illness)
- quinidine (a medicine used to treat irregular heartbeat).

Check with your doctor if:

- have allergies to any other substances, such as foods, preservatives, or dyes.
- are taking medicines for any other conditions
- you have or have had any chronic illness.
- have liver and/or Kidney problems. Your doctor may reduce the dose of OZOLE.
- have heart problems
- have kidney problems
- You are an elderly person above 65 years of age
- You have been diagnosed to have AIDS
- You have had any altered blood electrolyte levels
- You have been diagnosed to have cancer.

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.

Your doctor may need to monitor the function of the liver using blood tests. Be sure to follow the doctor's advice if regular checks on your liver are recommended.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

OZOLE use should be avoided during pregnancy except on doctor's advice for severe or life-threatening infections. Effective contraception should be used in women of childbearing potential and should continue throughout the treatment period and for approximately 1 week after the final dose. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor about the need for an additional method of contraception while being given OZOLE.

OZOLE may decrease the effectiveness of some birth control pills.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

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.

OZOLE is not recommended for use whilst breastfeeding however your doctor can discuss with you the risks and benefits involved.

3. What if I am taking other medicines?

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

Some medicines should not be taken with OZOLE.

These are listed under Section 2. What should I know before treatment with OZOLE.

Some medicines and OZOLE may interfere with each other . 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.

- Blood thinning medicines (warfarin or coumarin drugs)
- Some diabetes medicines (such as chlorpropamide, glibenclamide, glipizide or tolbutamide)
- Water tablets (diuretics, e.g., furosemide, hydrochlorothiazide)
- Some benzodiazepines (such as midazolam used as tranquillizers)
- Lemborexant (used to treat insomnia or sleeping difficulties)
- Phenytoin, valproic acid (used to treat convulsions)
- Some drugs used for heart problems, such as quinidine, amiodarone 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 ciclosporin, tacrolimus, sirolimus or tofacitinib
- Theophylline (medicines used to treat asthma)
- Prednisone (used to treat inflammation or supress the immune system)
- 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)
- Carbamazepine (used for treatment of epilepsy and bipolar disorder)
- Calcium channel blockers (used as anti-hypertensive drugs)
- ivacaftor (used to manage cystic fibrosis)
- lurasidone (used to manage schizophrenia)
- NSAIDs such as naproxen, diclofenac and celecoxib
- Cyclophosphamide, vincristine, vinblastine, olaparib or irbrutinib (used as to treat certain types of cancers)
- Tolvaptan (used to treat low levels of sodium in your blood or for kidney problems)
- Opioid pain killers such as alfentanil, fentanyl and methadone
- Halofantrine (used to treat malaria)
- some medicines used to lower cholesterol, such as atorvastatin, simvastatin or fluvastatin
- Losartan (used to treat high blood pressure)
- Vitamin A
- Antidepressants such as amitriptyline and nortriptyline.

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.

4. How do I use OZOLE?

How much to take

- Your doctor will tell you how much of this medicine you should take. This will 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.

When to take OZOLE

Take this medicine at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

It does not matter if you take it before, with or after food.

How to take it

Swallow the capsules whole with water.

How long to take it

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.

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

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 OZOLE

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time.

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

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

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 use too much OZOLE

If you think that you have used too much OZOLE, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using OZOLE?

Things you should do

- If you are a woman of child-bearing age, you should avoid becoming pregnant while taking OZOLE. Talk to your doctor about the need for an additional method of contraception while being given OZOLE.

  If you do become pregnant while taking OZOLE, tell your doctor immediately.
- If you suffer from HIV or have a weakened immune system and develop a rash while taking OZOLE, tell your doctor immediately.

  If this rash worsens, OZOLE may need to be stopped.
- Be sure to follow your doctor's advice if regular checks on your liver are recommended. In rare cases, OZOLE may affect the liver and may need to be stopped.
- If you have a pre-existing heart disease or any abnormalities of rhythm then you should follow up with your doctor regularly.
- If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.
- Remind any doctor, dentist, or pharmacist you visit that you are using OZOLE.

Things you should not do

- Do not start treatment if you have ever had an allergic reaction to any medicine containing fluconazole, any of the ingredients listed at the end of this CMI

- 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 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 OZOLE to treat any other medical complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive operate machinery as occasional dizziness or seizures may occur.

Drinking alcohol

No information available.

Looking after your medicine

Keep your medicine in the pack until it is time to take it.

If you take it out of the pack it may not keep well. Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink,
- in the car or on window sills. Heat and dampness can destroy some medicines.

Store OZOLE below 25°C.

Do not use this medicine 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 use this medicine if the packaging is torn or shows signs of tampering.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

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

Less serious side effects

Less serious side effects	What to do
• 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 • 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	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
• Symptoms of an allergic reaction which may include rashes, hives, itching, chest constriction, shortness of breath or swelling	**Call your doctor straight away, or go straight to the Emergency**

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) 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	**Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What OZOLE contains

Active ingredient (main 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
Other ingredients (inactive ingredients)	• lactose monohydrate • maize starch • colloidal anhydrous silica • magnesium stearate • sodium lauryl sulfate • Tek Print SW-9008 Black Ink. The capsule shells contain: • Patent blue • titanium dioxide • gelatin • erythrosine (100mg * 200mg only)
Potential allergens	Sugars as lactose May contain traces of sulfites and phenylalanine

Do not take this medicine if you are allergic to any of these ingredients.

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

What OZOLE looks like

50 mg capsules – 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.

AUST R – 122901

Available in blister packs of 28 capsules.

100 mg capsules – 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.

AUST R – 122903

Available in blister packs of 28 capsules.

200 mg capsules – 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.

AUST R – 122909

Available in blister packs of 28 capsules.

Who distributes OZOLE

Sun Pharma ANZ Pty Ltd

Suite 2.02, Level 2

12 Waterloo Road

Macquarie Park NSW 2113

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