

Consumer Medicine Information

Ozole

Fluconazole (flu-con-a-zole)

Capsules 150 mg

What is in this leaflet

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 it is expected to have for you.

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

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

What Ozole is used for

Ozole 150 mg is used to treat vaginal thrush, a yeast infection of the vagina.

Ozole is a member of a group of medicines called azole antifungals.

It works by stopping the growth of the fungal and yeast organisms causing your infection.

Ask your doctor or pharmacist if you have any questions about why Ozole has been recommended for you.

Ozole 150 mg is only available from a pharmacist and your pharmacist's advice is required.

This medicine is not addictive.

What is vaginal thrush

Vaginal thrush is a fungal infection of the vagina caused by the yeast named *Candida albicans*.

Some common symptoms of vaginal thrush are:

- vaginal itching or soreness
- pain during intercourse
- a white, odourless, discharge from the vagina (like cottage cheese)

Rubbing and scratching can aggravate the soreness and itching. Also, the salt of urine can sting the sore tissue.

Tell your doctor or pharmacist if you are experiencing any of the following symptoms:

- abnormal or irregular vaginal bleeding or blood stained discharge
- vulval or vaginal sores, ulcers or blisters
- lower abdominal pain or burning when passing urine

These are not usually symptoms of vaginal thrush, and you may need your doctor's or pharmacist's advice on the problems you are experiencing.

Ways to avoid thrush in the future

- Wear cotton briefs, stockings and loose-fitting clothing rather than tight synthetic clothing.
- Wash regularly but do not wash and dry yourself harshly.
- Avoid perfumed soaps, bath additives and vaginal deodorants.

Before you take Ozole

When you must not take it

Do not take Ozole if you have an allergy to:

- any medicine containing fluconazole
- any other medicine that is related to fluconazole. Examples are: miconazole, ketoconazole or clotrimazole
- any of the ingredients listed under Product Description

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 Ozole if you are taking cisapride which is a treatment for stomach problems.

Do not take this medicine if the expiry date printed on the packaging has passed 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.

Ozole is not recommended for children under 18 years of age, unless it has been recommended by your doctor.

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.

Tell your doctor or pharmacist if you have had thrush more than twice in the last 6 months.

Tell your doctor or pharmacist if you have previously developed a rash while taking fluconazole.

Tell your doctor if you have any other problems with your health such as:

- problems with your liver
- problems with your heart
- severe kidney problems
- you have AIDS

Tell your doctor if you plan to become pregnant, or are pregnant or 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 taking Ozole.

Taking other medicines

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

Ozole may interfere with some medicines. These include:

- some medicines used to treat symptoms of allergy.
- some medicines used to treat diabetes. Examples are: glibenclamide, glipizide, and tolbutamide.
- antibiotics and antiviral medicines. Examples are: rifabutin, rifampicin, amphotericin B, erythromycin or zidovudine.
- medicines used to treat problems with the immune system. Examples are: cyclosporine, tacrolimus or sirolimus.
- phenytoin used to control symptoms of epilepsy.
- theophylline used to control asthma symptoms.
- benzodiazepines, for example midazolam and triazolam.
- hydrochlorothiazide used to treat fluid problems.
- birth control (contraceptive) tablets.
- Losartan used to treat high blood pressure
- antidepressants such as amitriptyline and nortriptyline.
- carbamazepine used to treat epilepsy and bipolar disorder.
- NSAIDs such as naproxen, diclofenac and celecoxib.
- opioid pain killers such as methadone, alfentanil and fentanyl.
- warfarin used to stop blood clots.

Tell your doctor or pharmacist if you are taking warfarin as bleeding or bruising may occur.

These medicines may be affected by Ozole or may affect how well it works. You may need different amounts of your medicines, 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 and pharmacist have more information on medicines to be careful with or to avoid while taking Ozole.

How to take Ozole

Follow all directions given to you by your doctor and/or pharmacist carefully. They may differ from the information in this leaflet.

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

How much to take

The complete Ozole treatment for thrush is one 150 mg capsule. Take only one capsule.

After taking the Ozole capsule, the symptoms of thrush usually start to disappear in about one day.

How to take it

Swallow the capsule whole with water.

When to take it

This medicine can be taken before or after food, at any time of day.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (ph 0800 POISON or 0800 764 766) for advice if you think 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.

While you are taking it

Things you must do

If your symptoms do not begin to improve within a few days, or they become worse, tell your doctor.

Things you must not do

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.

Things to be careful of

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

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.

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.

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:

- 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.
- yellowing of the skin or eyes, also called jaundice.

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 using Ozole

Storage

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

Keep Ozole capsules in a cool, dry place where the temperature stays below 25°C.

Do not store your 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 your medicine where young children cannot reach it. A locked cupboard is a good place to store medicines.

Disposal

If this medicine has passed its expiry date, ask your pharmacist how to dispose of it.

Product description

What it looks like

- Ozole 150 mg - blue cap and body printed Ranbaxy on both cap and body.

Ingredients

Active ingredients

- 150 mg fluconazole in each capsule

Other ingredients

The ingredients present inside the OZOLE 150 mg capsule include: lactose monohydrate, maize starch, sodium lauryl sulfate, colloidal anhydrous silica, and magnesium stearate. In addition, the capsules shells contain: gelatin, patent blue (E133) and titanium dioxide (E171). The black colour in the printing ink is black iron oxide (E172).

Distributor

Ozole is supplied in New Zealand by:

Douglas Pharmaceuticals Ltd
P.O. Box 45 027
Auckland 0651
Phone (09) 835 0660

Date of Preparation

1 July 2011