

AVEZOL CAPSULE 150MG

Fluconazole (150mg)

What is in this leaflet

1. What Avezol is used for
2. How Avezol works
3. Before you use Avezol
4. How to use Avezol
5. While you are using Avezol
6. Side effects
7. Storage and disposal of Avezol
8. Product description
9. Manufacturer
10. Product registration holder
11. Date of revision
12. Serial number

What Avezol is used for

AVEZOL is one of a group of medicines called “antifungals”. The active ingredient is fluconazole. AVEZOL is used to treat infections caused by fungi including yeasts. The most common cause of fungal infections is a yeast called Candida. You may be given this medicine by your doctor to treat genital thrush, an infection of the vagina or penis.

How Avezol works

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

Before you use Avezol

- When you must not use it

Do not take AVEZOL if you

- have ever had an allergic reaction to:
 - any of the ingredients of AVEZOL
 - other medicines you have taken to treat a fungal infection.

The symptoms may include itching, reddening of the skin or difficulty in breathing.

- are taking terfenadine (an antihistamine for allergies)
- are taking cisapride (used for stomach upsets)

- Before you start to use it

Tell your doctor if you:

- are aged under 16 years
- have liver or kidney problems
- suffer from heart disease, including heart rhythm problems
- have abnormal levels of potassium, calcium or magnesium in your blood

Inform your doctor if you have such conditions:

- Pregnant or planning to become pregnant

Avezol may cause harm to your unborn baby. You should not take Avezol while you are pregnant unless your doctor has told you to. Inform your doctor if you are pregnant or planning to become pregnant.

If you are a woman of child-bearing potential, avoid becoming pregnant during treatment. Use effective contraception during treatment and for 1 week after treatment.

- Breast-feeding

Avezol is excreted in human breast milk, hence its use in nursing mothers is not recommended. However, breast-feeding may be maintained if you took a single dose of Avezol 150mg. Breast-feeding is not recommended after a high dose (more than 150 mg) or repeated use of Avezol.

- Taking other medicines

Tell your doctor, immediately if you are taking Terfenadine (an antihistamine for treating allergies) or Cisapride (used for stomach upsets) as these should not be taken with AVEZOL.

There are some medicines that may interact with AVEZOL. Make sure your doctor knows if you are taking any of the following medicines:

- warfarin (or similar drugs) that thin the blood to prevent blood clots
- medicines for diabetes such as chlorpropamide, glibenclamide, glipizide or tolbutamide

- water tablets, such as hydrochlorothiazide, used to treat fluid retention and high blood pressure
- midazolam used to help you sleep or for anxiety
- phenytoin (used to control epilepsy)
- rifampicin or rifabutin (antibiotics for infections)
- ciclosporin or tacrolimus (to prevent transplant rejection)
- theophylline (used to control asthma)
- astemizole (an antihistamine for treating allergies)
- zidovudine, also known as AZT (used in HIV-infected patients)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

How to use Avezol

- How much to use

Always take AVEZOL exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Swallow the capsule whole with a glass of water.

You can take your medicine with or without a meal at any time of day.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

The whole course of treatment for vaginal thrush or penis thrush infection (candidal balanitis) is one capsule which you take by mouth.

Vaginal Thrush

Your condition should start to clear up within a few days - some women notice an improvement in one day.

AVEZOL CAPSULE 150MG

Fluconazole (150mg)

If your condition does not clear up within a few days you should go back to your doctor.

Penis Thrush infection

Your condition should start to clear up within a few days but it may take up to a week.

If your condition has not cleared up after one week, you should go back to your doctor.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember.

- If you use too much (overdose)

Taking too much AVEZOL may make you unwell. Contact your doctor or your nearest hospital casualty department at once.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Avezol.

- Things you must not do

You should not take AVEZOL while you are pregnant or if you are breast feeding.

- Things to be careful of

Treatment with AVEZOL is unlikely to affect your ability to drive or use machinery.

This medicine contains a small amount of lactose (sugar), if you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking this medicine.

Side effects

Like all medicines, **AVEZOL** can cause side effects, although not everybody gets them.

A few people develop **allergic reactions** although serious allergic reactions are rare. If you get any of the following symptoms, **tell your doctor immediately.**

- Sudden wheezing, difficulty in breathing or tightness in chest
- Swelling of eyelids, face or lips
- Itching all over the body reddening of the skin or itchy red spots
- Skin rash
- Severe skin reactions such as a rash that causes blistering (this can affect the mouth and tongue).
- If you are an AIDS patient you are more likely to get severe skin reactions to drugs including **AVEZOL.**

Very common side effects which may affect more than 1 person in 10 are listed below:

- feeling sick
- stomach discomfort
- diarrhoea
- wind
- rash
- headache

These undesirable effects are usually mild. If they cause you discomfort or are long lasting, check with your doctor or pharmacist.

Other side effects

- itching
- being sick
- seizure
- lower than normal white blood cells that help defend against infections and blood cells that help to stop bleeding
- high blood levels of cholesterol, fats or salt
- liver damage and yellowing of the skin and eyes (Jaundice)
- hair loss
- dizziness
- altered sense of taste

- change in heart rate or rhythm

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Avezol

- Storage

Keep them out of the reach of the children.

Do not store in temperature over 30°C. Keep it at its original pack. Protect it from light and humidity. Do not use it after its expiring date, recorded on the packaging.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

- What it looks like

Avezol 150 mg capsules are turquoise hard gelatin capsule, size 1, containing white to off-white powder. Avezol 150 comes in a blister pack containing one capsule.

- Ingredients

Active ingredient

Fluconazole

Inactive ingredients

Lactose, Maize starch, Colloidal silicon dioxide, Magnesium stearate, Sodium lauryl sulphate

Capsule Body composition

Titanium dioxide, Erythrosine E127,

AVEZOL CAPSULE 150MG

Fluconazole (150mg)

Brilliant Blue FCF-FD&C Blue,
Gelatin

Cap

Titanium dioxide, Erythrosine E127,
Brilliant Blue FCF-FD&C Blue 1,
Gelatin

- MAL number:

MAL07082863ACZ

Manufacturer

Delorbis Pharmaceuticals Ltd.
17 Athinon Street,
Ergates Industrial Area,
2643 Ergates,
2081 Lefkosia,
Cyprus, European Union.

Product Registration Holder

Apex Pharmacy Marketing Sdn Bhd
No. 2, Jalan SS13/5,
47500 Subang Jaya,
Selangor Darul Ehsan,
Malaysia.

Date of revision

26/11/2019

Serial Number

NPRA(R2/1)191120/291