

BIOZOLE CAPSULE

Fluconazole (50mg, 100mg, 150mg and 200mg)

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What *Biozole* is used for

Biozole is used to treat the following types of fungal infections.

- Fungal infection of the vagina.
- Fungal infection of the mouth or throat.
- Skin infections
- Internal fungal infections caused by:
 - *Candida* and found in the blood stream, body organs or urinary tract.
 - *Cryptococcus*, e.g. meningitis and infections of other sites such as the lungs and skin. *Biozole* also be used to stop an infection caused by *Cryptococcus* from coming back (in AIDS patient).

How *Biozole* works

Fluconazole is a potent antifungal agent.

Before you use *Biozole*

- When you must not use it

Do not use *Biozole* if you are hypersensitive to fluconazole or other related azole compound.

Pregnancy and lactation

Inform your doctor if you have such conditions:

- Pregnant or planning to become pregnant

Biozole may cause harm to your unborn baby. You should not take *Biozole* 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

Biozole 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 *Biozole* 150mg. Breast-feeding is not recommended after a high dose (more than 150 mg) or repeated use of *Biozole*.

- Before you start to use it

Please tell your doctor before taking *Biozole* if :

- You have liver or kidney problems.

- Taking other medicines

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

- Blood thinning agent (for warfarin)
- Sulfonylureas (for diabetes)
- Hydrochlorothiazide (for high blood pressure)
- Phenytoin (for anti-seizure)
- Oral contraceptives pill
- Rifampicin (for bacterial infections)
- Zidovudine (for HIV/AIDS)
- Cyclosporine (for immunosuppressant)
- Terfenadine (for allergic)
- Theophylline (for respiratory diseases)

How to use *Biozole*

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

The daily dose of fluconazole should be based on the nature and severity of the fungal infection.

Use in Adults:

The doctor will prescribe a suitable dose according to your condition. The dose may vary from 50 mg to 400 mg taken once daily or as single dose depending on your condition.

Use in Children:

The dose is 3-12 mg/kg daily, depending on severity of the disease.

Use in elderly and renal impairment:

Dosage adjustment is required for elderly and individuals with kidney impairment. You will be advised accordingly by your doctor and pharmacist.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking *Biozole* for as long as your doctor recommends.

- 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 it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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 *Biozole*.

Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give *Biozole* to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Driving and using machines

If the tablets make you feel sick, dizzy or tired, or give you a headache, do not drive or use machines and contact your doctor immediately.

Side effects

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Common:

- Nausea
- Headache
- Abdominal pain
- Diarrhea
- Flatulence
- Rash

For individuals with AIDS

- Exfoliative cutaneous reactions

For individuals with invasive/systemic fungal infections develop rashes

- Bullous lesions/erythema multiforme
- Anaphylaxis (rare)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835549, or visiting the website portal.npra.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

Storage and Disposal of *Biozole*

- Storage

Keep out of the reach and sight of children.

Store below 30 °C.

- 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

BIOZOLE 50 mg: White powder filled in light blue (cap) / white (body), opaque, hard gelatin No.4 capsules printing in black Biolab's logo on one side and "BIOLAB" on the other.

BIOZOLE 100 mg: White powder filled in blue (cap) / white (body), opaque, hard gelatin No.2 capsules printing in black Biolab's logo on one side and "BIOLAB" on the other.

BIOZOLE 150 mg: White powder filled in pink (cap) / pink (body), opaque, hard gelatin No.1 capsules printing in black "BIOZOLE" on one side and "150" on the other.

BIOZOLE 200 mg: White powder filled in purple (cap) / white (body), opaque, hard gelatin No.0 capsules printing in black Biolab's logo on one side and "BIOLAB" on the other.

- Ingredients

- Active ingredient(s)
Fluconazole

- Inactive ingredients
Lactose, Pregelatinized Starch, Colloidal Silicon Dioxide and Magnesium Stearate

- MAL numbers:

Biozole 50 mg : MAL 20040103AZ

Biozole 100 mg: MAL 20040106AZ

Biozole 150 mg: MAL 20040110AZ

Biozole 200 mg: MAL 20040113AZ

Manufacturer

Biolab Company Ltd
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Product Registration Holder

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