

FLUCOZOLE CAPSULE

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

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What Fluconazole is used for

Fluconazole is used to treat fungal and yeast infection. It is also used to prevent you from getting fungal infection (if your immune system is weak). The most common cause of fungal infection is a yeast called *Candida*.

How Fluconazole works

Fluconazole belongs to a group of medicines called “antifungal”. Fluconazole kills fungal and yeast causing your infection.

Before you use Fluconazole

- When you must not use it

Do not take this medicine if:

- You are allergic to fluconazole, other antifungals, or any other ingredients listed at the end of this leaflet

Do not take these medicines without consulting doctor:

- Terfenadine, astemizole (to treat allergies)
- Cisapride (to treat stomach problem)
- Pimozide (to treat mental illness)
- Quinidine (to treat irregular heartbeat)
- Erythromycin (antibiotics)

- Before you start to use it

Pregnant or planning to become pregnant

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

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

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

- hormonal problems
- liver problems that may cause lack of energy, loss of appetite, nausea, vomiting and jaundice (yellowing of the skin)
- kidney problems
- heart disease, including heart rhythm problems
- severe skin reaction (itchiness, skin redness or breathing difficulty)
- ringworm of scalp
- galactose-intolerant (fluconazole contains lactose)

- Taking other medicines

Tell your doctor if you are taking any other medicines. This includes:

- Rifampicin, rifabutin, azithromycin (antibiotics)
- Halofantrine (to treat malaria)
- Amiodarone (to treat irregular heartbeat)
- Hydrochlorothiazide, nifedipine, isradipine, amlodipine, verapamil, felodipine, losartan (medicines for high blood pressure)
- Alfentanil, fentanyl (used as anaesthetic)
- Amitriptyline, nortriptyline (to treat depression)
- Amphotericin B, voriconazole (antifungals)
- Warfarin or similar medicines (to prevent blood clots)
- Benzodiazepines, e.g. midazolam or triazolam (used for anxiety or help you sleep)
- Carbamazepine, phenytoin (to treat epilepsy)

- Celecoxib, naproxen, lornoxicam, meloxicam, diclofenac (painkillers)
- Cyclophosphamide, vinca alkaloids, e.g. vincristine, vinblastine (used to treat cancer)
- Statins, e.g. atorvastatin, fluvastatin, simvastatin (used to reduce high cholesterol levels)
- Olaparib (used to treat ovarian cancer)
- Cyclosporine, sirolimus, tacrolimus (to prevent transplant rejection)
- Methadone (used for pain or to treat drug addiction)
- Oral contraceptives (to prevent pregnancy)
- Prednisone (steroid to reduce inflammation)
- Saquinavir, zidovudine (medicines for HIV infection)
- Chlorpropamide, glibenclamide, glipizide, tolbutamide (medicines for diabetes)
- Theophylline (used to control asthma)
- Tofacitinib (to treat rheumatoid arthritis)
- Vitamin A (nutritional supplement)
- Ivacaftor (to treat a rare genetic disease known as cystic fibrosis)

How to use Fluconazole

- How much to use

Adult

The doctor will prescribe a suitable dose according to your condition. It usually ranges from 50 mg to 400 mg once daily.

Children

Single daily dose. Your doctor will determine the right dose according to your child's bodyweight and condition.

Elderly

The usual adult dose shall be used unless you have kidney problems.

Individual with kidney problem

Your doctor will adjust the dose, depending on your kidney function.

- When to use it

The capsules should be swallowed whole with or without food or as directed by your doctor.

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- How long to use it

Use Flucozole for the duration that the doctor recommends. Depending on your condition, the duration of treatment may range from 7 days to 8 weeks.

- 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 have taken too much.

Do this even if there are no signs of discomfort or poisoning. You may need immediate medical attention. Taking too many capsules may cause hallucination and changes in behaviour.

While you are using it

- Things you must do

- Use Flucozole only with a doctor's prescription
- Use your medicine exactly as your doctor has told you so
- Tell the doctors, dentists and pharmacists who is treating you that you are using Flucozole
- Tell your doctor immediately if you become pregnant while using this medicine

- Things you must not do

- Do not stop using this medicine unless advised by your doctor
- Do not use any new medicine without consulting your doctor or pharmacist
- Do not give Flucozole to anyone else, even if they have the same signs and symptoms as you

- Things to be careful of

This medicine may affect your ability to drive or use machines.

If the capsules make you feel dizzy or if you experience seizure, do not drive or use machines and contact your doctor immediately.

Side effects

Please get medical help immediately if you feel unwell while taking Flucozole.

Common side effects:

- headache
- abdominal pain, diarrhoea
- nausea, vomiting
- rashes
- increases in blood tests of liver function

Uncommon side effects:

- itchiness, hives, increased sweating
- decreased appetite
- unable to sleep, feeling drowsy
- dizziness, spinning sensation
- constipation, indigestion, wind, dry mouth
- liver damage and yellowing of the skin and eyes
- reduction in red blood cells which can make skin pale and cause weakness or breathlessness
- seizures
- pricking or numbness, changes in sense of taste
- muscle ache
- fatigue, feeling discomfort, lack of energy, fever

Rare side effects:

- Sudden wheezing, difficulty in breathing or tightness in the chest
- change in heart rate or rhythm
- severe skin reaction such as a rash that causes blistering
- swelling of eyelids, face or lips
- hair loss
- liver failure
- shaking
- low blood potassium
- high blood levels of cholesterol
- red or purple discoloration of the skin which may be caused by low platelet count, or other blood cell changes

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

Storage and Disposal of Flucozole

- 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 for disposal of the medicines you no longer need. This will help protect the environment.

Product Description

- What it looks like

Flucozole 50 mg Capsule

White granule in blue-white capsule No. 4 with letter 50 and SIAM logo in black ink on the capsule shell.

Flucozole 100 mg Capsule

White granule in blue-white capsule No. 2 with letter 100 and SIAM logo in black ink on the capsule shell.

Flucozole 150 mg Capsule

White granule in blue-white capsule No. 1 with letter 150 and SIAM logo in black ink on the capsule shell.

Flucozole 200 mg Capsule

White granule in violet-white capsule No. 0 with letter 200 and SIAM logo in black ink on the capsule shell.

- Ingredients

Active ingredient: Fluconazole

Inactive ingredients: lactose monohydrate, magnesium stearate, povidone, sodium starch glycolate

Capsule shell: gelatin, titanium dioxide, brilliant blue FCF - FD&C Blue 1, Erythrosine – FD&C Red 3.

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- MAL number

Fluconazole 50 mg Capsule
MAL06121030AZ

Fluconazole 100 mg Capsule
MAL06121027AZ

Fluconazole 150 mg Capsule
Pending

Fluconazole 200 mg Capsule
MAL06121028AZ

Manufacturer

Siam Bheasach Co., Ltd. 123 Soi
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Product Registration Holder

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