

Fluconazol

50mg Capsules

Composition:

Each hard gelatin capsule contains:

Fluconazole BP 50 mg
Excipients q.s.

Approved colorants are used in the capsule.

Therapeutic indications

Fluconazole capsules are indicated for the following fungal infections:

Fluconazole capsules are indicated in adults for the treatment of:

- Cryptococcal meningitis
- Coccidioidomycosis
- Invasive candidiasis.
- Mucosal candidiasis, including oropharyngeal and esophageal candidiasis, candiduria, and chronic mucocutaneous candidiasis.
- Chronic oral atrophic candidiasis (denture sore mouth) if dental hygiene or topical treatment is insufficient.
- Acute or recurrent vaginal candidiasis; when local therapy is not appropriate.
- Balanitis caused by Candida; when local therapy is not appropriate.
- Dermatomycosis, including infections caused by *tinea pedis*, *tinea corporis*, *tinea cruris*, *tinea versicolor*, and dermal *Candida* when systemic therapy is indicated.
- *Tinea unguium* (onychomycosis) when other agents are not considered suitable.

Fluconazole capsules are indicated in adults for the prophylaxis of:

- Relapse of cryptococcal meningitis in patients at high risk of recurrence.
- Relapse of oropharyngeal or esophageal candidiasis in HIV-infected patients at high risk of relapse.
- Reducing the incidence of recurrent vaginal candidiasis (4 or more episodes per year).
- Prophylaxis of *Candida* infections in patients with prolonged neutropenia (such as patients with hematological malignancies undergoing chemotherapy or patients undergoing hematopoietic stem cell transplantation). Fluconazole capsules are indicated for full-term newborns, infants, young children, and adolescents aged 0 to 17 years.
- Fluconazole capsules are used to treat mucosal candidiasis (oropharyngeal, esophageal), invasive candidiasis, and cryptococcal meningitis, and for the prophylaxis of candidiasis infections in immunocompromised patients.
- Fluconazole capsules may be used as maintenance therapy to prevent the recurrence of cryptococcal meningitis in children at high risk of relapse. Therapy may be initiated before culture results and other laboratory findings are available; however, once results are available, anti-infective therapy should be adjusted accordingly. Official guidelines regarding the appropriate use of antifungals should be considered.

Contraindications:

Based on the results of a multiple-dose interaction study, the concomitant administration of terfenadine is contraindicated in patients receiving multiple-dose Fluconazole regimens of 400 mg per day or higher. Co-administration of other drugs known to prolong the QT interval and metabolized via cytochrome P450 (CYP) 3A4—such as cisapride, astemizole, pimozide, quinidine, and erythromycin—is contraindicated in patients treated with Fluconazole.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Fluconazole capsules if:

- You suffer from liver or kidney problems

- You suffer from heart disease, including heart rhythm problems
- You have abnormal levels of potassium, calcium, or magnesium in your blood
- You develop severe skin reactions (itching, skin redness, or difficulty breathing)
- You develop signs of "adrenal insufficiency," where the adrenal glands do not produce adequate amounts of certain steroid hormones, such as cortisol (chronic or long-lasting fatigue, muscle weakness, loss of appetite, weight loss, abdominal pain).

Pregnancy, breastfeeding, and fertility

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, consult your doctor or pharmacist before taking this medicine. You should not take Fluconazole capsules while pregnant unless your doctor has told you to. You may continue breastfeeding after taking a single 150 mg dose of Fluconazole capsules. You should not breastfeed if you are taking repeated doses of Fluconazole capsules.

Consult your doctor or pharmacist before taking any medication.

Storage: Do not store above 30°C; store in a dry place and protect from light.

Presentation: Blister pack of 10 capsules.

Keep out of the reach of children.

Manufactured by:

