

COMPOSITION

Defungi 50 Capsule: Each capsule contains Fluconazole USP 50 mg.

Defungi 150 Capsule: Each capsule contains Fluconazole USP 150 mg.

PHARMACOLOGY

Defungi (Fluconazole) is a triazole antifungal agent. It is a potent inhibitor of fungal cytochrome P-450 dependent enzymes. Cytochrome P-450 enzyme system is essential component of fungal cell membrane which is responsible for the synthesis of ergosterol.

INDICATIONS

It is indicated for the treatment of vaginal candidiasis, oropharyngeal and esophageal candidiasis and cryptococcal meningitis. It is also effective for the treatment of urinary tract infection caused by candida, peritonitis and systemic candida infections (including candidemia, disseminated candidiasis and pneumonia).

DOSAGE AND ADMINISTRATION

Adult:

Vaginal candidiasis: 150 mg as a single oral dose.

Oropharyngeal candidiasis: 200 mg on the first day, followed by 100 mg once daily. Clinical evidence of this infection generally resolves within several days, but treatment should be continued for at least 2 weeks to decrease the likelihood of relapse.

Esophageal candidiasis: 200 mg on the first day, followed by 100 mg once daily. Doses up to 400 mg/day may be used. Patients should be treated for a minimum of three weeks and for at least two weeks following resolution of symptoms.

Systemic candida infections: Optimal therapeutic dosage and duration of therapy have not been established. Sometimes, doses of up to 400 mg daily have been used.

Urinary tract infections caused by candida and peritonitis: 50-200 mg daily have been used.

Cryptococcal meningitis: 400 mg on the first day, followed by 200 mg once daily.

Prophylaxis in patients undergoing bone marrow transplantation: 400 mg once daily.

Child:

Doses of 3-6 mg/kg daily have been used. Doses up to 12 mg/kg is recommended.

CONTRAINDICATIONS

It should not be used in patients with known hypersensitivity to Fluconazole or to related triazole compounds.

WARNING AND PRECAUTION

Fluconazole should be administered with caution to patients having pro-arrhythmic conditions.

SIDE EFFECTS

Angioedema and anaphylactic reactions were reported in rare cases.

USE IN PREGNANCY AND LACTATION

US FDA Pregnancy category of Fluconazole is C. So, Fluconazole should be avoided in pregnancy and lactation unless the potential benefits to the other outweigh the possible risks to the fetus.

USE IN CHILDREN AND ADOLESCENTS

Safety and efficacy have not been established under the age of 6 months.

DRUG INTERACTIONS

Concomitant use of cyclosporin or phenytoin with Fluconazole increases the plasma level of cyclosporin or phenytoin. Concomitant use of Fluconazole and Warfarin prolongs the prothrombin time. Rifampicin level is decreased when used with Fluconazole.

OVERDOSAGE

Consult a registered physician immediately in case of hypersensitivity reactions.

STORAGE

Store below 30°C temperature in a cool & dry place. Protect from light & moisture. Keep out of the reach of children.

HOW SUPPLIED

Defungi 50 Capsule: Each box contains 30's capsules in Alu-Alu blister pack.

Defungi 150 Capsule: Each box contains 10's capsules in Alu-Alu blister pack.