

Flucanex™

Fluconazole

Composition:

Flucanex™ 50 Capsule: Each capsule contains Fluconazole USP 50 mg.

Flucanex™ 150 Capsule: Each capsule contains Fluconazole USP 150 mg.

Description:

Flucanex™ (Fluconazole) is a triazole antifungal drug that acts by inhibition of the ergosterol component of the fungal cell membrane. Ergosterol is integral to the proper functioning of the cell membrane so inhibition of its synthesis leads to a cascade of abnormalities in permeability, membrane-bound enzyme activity and co-ordination of chitin synthesis, leading to inhibition of growth, abnormal cell wall formation and accumulation of intracellular lipids and membranous vesicles. It is active against a broad spectrum of yeast and other fungal pathogens and normally administered orally.

Indications:

It is indicated for the treatment of Vaginal candidiasis /candidal balanitis.

Mucosal candidiasis: Oropharyngeal candidiasis, oesophagitis, candiduria & systemic candidal infections (including candidaemia and disseminated candidiasis).

Tinea pedis, tinea corporis, tinea cruris, pityriasis versicolor, dermal candidiasis.

Cryptococcal infections (including meningitis).

Prevention of fungal infections in immunocompromised patients.

Dosage & Administration:

Adult:

Vaginal candidiasis & candidal balanitis: a single dose of 150 mg.

Mucosal candidiasis (except genital): 50 mg daily (100 mg daily in unusually difficult infections)

Oropharyngeal candidiasis: 50 mg is given for 7-14 days.

Systemic candidal infections & cryptococcal infections (including meningitis): 400 mg on first day then 200 mg to 400 mg daily; max. 800 mg daily in severe infections; treatment continued according to response (at least 8 weeks for cryptococcal meningitis).

Tinea pedis, tinea corporis, tinea cruris, pityriasis versicolor & dermal candidiasis: 50 mg daily for 2-4 weeks (for up to 6 weeks in tinea pedis); max. duration of treatment 6 weeks.

Prevention of fungal infections in immunocompromised patients: 50-400 mg daily adjusted according to risk;

400 mg daily if high risk of systemic infections e.g. following bone-marrow transplantation.

Children:

Mucosal candidiasis: Children: 3-6 mg/kg on first day then 3 mg/kg daily. Neonate: every 72 hours in neonate up to 2 weeks old & every 48 hours in neonate 2-4 weeks old.

Systemic candidal infections & cryptococcal infections (including meningitis): Children: 6-12 mg/kg daily. Neonate: every 72 hours in neonate up to 2 weeks old & every 48 hours in neonate 2-4 weeks old.

Prevention of fungal infections in immunocompromised patients: Children: according to extent and duration of neutropenia. 3-12 mg/kg daily. Neonate: every 72 hours in neonate up to 2 weeks old & every 48 hours in neonate 2-4 weeks old.

OR AS DIRECTED BY THE PHYSICIAN.

Side Effects:

Nausea, abdominal discomfort, diarrhea, flatulence, headache, rash, less frequently dyspepsia, vomiting, taste disturbance, hepatic disorders, hypersensitivity reactions, anaphylaxis, dizziness, seizures, alopecia, pruritus, toxic epidermal necrolysis, Stevens-Johnson syndrome, hyperlipidaemia, leucopenia, thrombocytopenia and hypokalaemia reported.

Precautions:

Caution should be taken in renal impairment patients.

Use in Pregnancy & Lactation:

Pregnancy: Multiple congenital abnormalities reported with long-term high doses, caution should be taken.

Lactation: Present in breast milk but amount probably too small to be harmful, caution should be taken.

Contraindications:

It is contraindicated to patients with hypersensitivity to this drug and in advanced liver diseases.

Storage Condition:

Store in a cool and dry place below 25 °C, protect from light. Keep out of the reach of children.

Presentation:

Flucanex™ 50 Capsule: Each box contains 5x6's capsules in Alu-Alu blister pack.

Flucanex™ 150 Capsule: Each box contains 1x6's capsules in Alu-Alu blister pack.

Manufactured by:

Julphar Bangladesh Ltd.

Sreepur, Gazipur, Bangladesh.