

FLUCOSTAN 50

Fluconazole INN 50mg Capsule

DESCRIPTION

FLUCOSTAN 50 (Fluconazole) is a triazole Antifungal agent. It is a potent and selective inhibitor of fungal cytochrome P-450 dependent enzymes necessary for the synthesis of ergosterol, a major component of the fungal cell membrane.

PHARMACOLOGY

FLUCOSTAN 50 (Fluconazole) is well absorbed following oral administration. From the oral route is 90% mean peak plasma concentration of hour per ml have been reported in healthy subjects following a 400 mg oral dose. Peak concentrations are reached within 1 to 2 hours of oral administration. The elimination phase half life ranges from 20 to 50 hours. **FLUCOSTAN 50** (Fluconazole) is widely distributed and achieves concentration in joint fluid, saliva, sputum, vaginal fluids and peritoneal fluid similar to those achieved in plasma. Concentration in the cerebrospinal fluid range from 50 to 90% of plasma concentrations. Protein binding is about 11%. 80% or more of **FLUCOSTAN 50** (Fluconazole) is excreted unchanged in the urine. **FLUCOSTAN 50** (Fluconazole) can be removed by dialysis.

INDICATIONS AND DOSAGE

The daily dose of **FLUCOSTAN 50** (Fluconazole) should be based on the nature and severity of the fungal infection. Most cases of fungal infections require multiple dose therapy. Treatment should be continued until clinical parameters or laboratory tests indicate that active fungal infection has subsided. And inadequate period of treatment may lead to recurrence of active infection.

Dosage	Recommended
Vaginal candidiasis	150 mg as a single dose
Oropharyngeal candidiasis	200 mg in 1 st day followed by 100 mg daily for 14 days
Oesophageal candidiasis	200 mg in 1 st day followed by 100 mg daily for 14-30 days
Systemic candidiasis and cryptococcal infection	400 mg in 1 st day followed by 200 mg daily for 28 days or longer based on clinical response
Tinea corporis/Tinea cruris/ Tinea pedis / others Tinea	150 mg in weekly for 4 to 6 week
Kerion	50 mg daily for 20 days
Pityriasis versicolor Onychomycosis	400 mg as a single dose. 150 mg weekly for 12 mg
Child over 1 year	
In Superficial candidiasis	1-2 mg/kg daily
In Systemic candidiasis and cryptococcal infection	3-6 mg/kg daily

OTHER USES

1. Fungal urinary tract infections
2. Disseminated candidiasis
3. Prophylaxis for fungal infection in neutropenic cancer patients
4. Acute treatment of other systemic fungal infections

USE IN THE ELDERLY

The normal dose should be used if there is no evidence of renal impairment.

USE IN RENAL IMPAIRMENT

No adjustment in single dose therapy is required. In multiple dose therapy normal doses should be given on days 1 and 2 of treatment and there after the dosage intervals should be modified depending on creatinine clearance.

EFFECTS ON LIVER

FLUCOSTAN 50 (Fluconazole) is not predictable hepatotoxic drug in human.

EFFECTS ON PREGNANT WOMEN

Adverse foetal effects have been seen in animal only at doses ranging from 80 mg/kg with maternal toxicity. These levels are 20-60 times the recommended therapeutic use. Still Fluconazole should be used in pregnancy only if the potential benefit justifies the possible risk to the fetus.

EFFECTS ON LACTATING MOTHERS

FLUCOSTAN 50 (Fluconazole) is secreted in human milk at concentrations similar to plasma. Therefore, the use of Fluconazole in nursing mother is not recommended.

CONTRAINDICATION

FLUCOSTAN 50 (Fluconazole) should not be used in patients with known hypersensitivity to Fluconazole or to related triazole compounds.

DRUG INTERACTIONS

FLUCOSTAN 50 (Fluconazole) acts by inhibiting fungal cytochrome P-450 enzymes. It interacts with drugs metabolized by cytochrome P-450, Cyclosporin, Phenytoin, Anticoagulants, Oral Hypoglycemic, Rifampicin and Oral contraceptives.

ADVERSE EFFECTS

Therapy with **FLUCOSTAN 50** (Fluconazole) is well tolerated. The incidence of side effects were 16% in 4000 patients treated with Fluconazole. The most common adverse effects are nausea (3.7%), abdominal pain (1.17%), vomiting (1.7%) and diarrhea (1.5%). Headache and skin rash were also seen.

PHARMACEUTICALS PRECAUTIONS

FLUCOSTAN 50 (Fluconazole) should be stored below 30°C.

COMMERCIAL PACK

FLUCOSTAN 50 : Each Box contains 4 x 5's capsules of Fluconazole INN 50 mg.

Manufactured by



Ziska Pharmaceuticals Ltd.
Kaliakoir, Gazipur, Bangladesh