

FLUNAC

Fluconazole USP Capsule & Suspension

Composition : Flunac-50 Capsule : Each capsule contains Fluconazole USP 50mg.

Flunac-150 Capsule : Each capsule contains Fluconazole USP 150mg.

Flunac Suspension : Each 5ml reconstituted suspension contains Fluconazole USP 50mg.

Pharmacology : Fluconazole a member of a new triazole class of antifungal agents, is a potent and selective inhibitor of fungal enzymes necessary for the synthesis of ergosterol. Fluconazole is a highly selective inhibitor of fungal cytochrome P450 dependent enzyme lanosterol 14- α -demethylase. It is extensively absorbed in the gastrointestinal tract when an oral dose is taken. The terminal elimination half-life in the plasma is approximately 30 hours (range: 20-50 hours) after oral administration.

Indications : It is used for the treatment of oropharyngeal, esophageal, vaginal mucosal or systemic candidiasis, esophagitis, candiduria, fungal urinary tract infection, Pneumonia and meningitis.

Dosage and administration : It is administered orally.

Adults & patients over 18 years : Mucosal candidiasis (except vaginal candidiasis)-Oropharyngeal candidiasis : the recommended dose is 50mg once daily for 7 to 14 days.

For other candidal infections of the mucosa e.g. oesophagitis, non-invasive bronchopulmonary infections, candiduria, mucocutaneous candidiasis etc.: the recommended dose is 50mg daily, given for 14 to 30 days. In unusually difficult cases of mucosal candidal infections the dose can be increased to 100mg daily.

Vaginal candidiasis : 150mg single oral dose.

Systemic candidiasis (Cryptococcal infections e.g., meningitis) : 400mg initially, then 200mg daily. The dose can be increased upto 400mg daily if necessary. Treatment should continue according to patient's response.

Child over 1 year : Superficial candidal infections, 1-2 mg/kg daily; systemic candidiasis and Cryptococcal infections-3-6mg/kg daily. In serious life threatening infections upto 12mg/kg daily has been given to children aged 5-13 years, maximum 400mg daily. Or, as directed by the registered physician.

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

Precautions : Fluconazole should be administered with caution to patients with renal dysfunction.

Side effects : The most common side-effects are those affecting the gastrointestinal tract, e.g., nausea, abdominal discomfort, diarrhoea and flatulence.

Use in pregnancy & lactation : Pregnancy : Pregnancy category C. There are no adequate and well controlled studies in pregnant woman. It should be used only if the potential benefit outweighs the potential risk to the fetus. Nursing mother : Caution should be exercised when it is administered to a nursing woman.

Use in child : See dosage and administration.

Drug interactions : Fluconazole increases the plasma concentration of cyclosporine, phenytoin, rifabutin. Theophylline AUC, C_{max} and half-life were significantly increased and clearance was decreased. Fluconazole resulted in significant increases in C_{max} and AUC of tolbutamide, glyburide and glipizide. A single warfarin dose after 14 days of Fluconazole resulted in an increase in the P.T. response.

Overdose : The symptoms of overdose with fluconazole accompanied by hallucination and paranoid behavior.

Storage : Store below 30°C in a dry place.

Packing : Flunac-50 Capsule : Each box contains 3 x 10's capsules in blister pack.

Flunac-150 Capsule : Each box contains 2 x 10's capsules in blister pack.

Flunac Suspension : Each bottle contains powder for the preparation of 35ml suspension.



Manufactured by
DRUG INTERNATIONAL LTD.
Tongi, Gazipur, Bangladesh

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