Flucoder®

Fluconazole USP Capsule & Powder for Suspension

DESCRIPTION

Flucoder® is a preparation of Fluconazole. It is a triazole antifungal drug that inhibits cytochrome P-450 dependent enzymes resulting in blockade of ergosterol synthesis. **Flucoder®** is well absorbed following oral administration and is widely distributed and achieves concentration in joint uid, saliva, sputum, vaginal uid and peritoneal uid in same concentration that is achieved in plasma.

INDICATIONS

Acute or recurrent vaginal candidiasis. Mucosal candidiasis e.g. oropharyngeal, oesophageal, bronchopulmonary, mucocutaneous, denture sore mouth. Tinea pedis, tinea corporis, tinea cruris, tinea versicolor and dermal candida infection. Systemic candidiasis including candidaemia, disseminated candidiasis and other forms of candidial infection. Cryptococcosis, cryptococcal meningitis and infections of other sites (pulmonary and cutaneous). For prevention of fungal infections in immunocompromised patients e.g. neutropanic cancer patients.

DOSAGE AND ADMINISTRATION

Adult

Acute and recurrent vaginal candidiasis : Orally a single dose 200 mg. Mucosal candidiasis (except vaginal): Orally 50 mg daily (100 mg daily in a single dose in unusually difficult infections) for 7-14 days. Oropharyngeal candidiasis maximum 14 days, in atrophic oral candidiasis with denture for 14 days, in oesophagitis and candiduria for 14-30 days. Tinea pedis, corporis, cruris, versicolor and dermal candidiasis: Orally 50 mg daily for 2-4 weeks (upto 6 weeks in tinea pedis) maximum duration of treatment is 6 weeks. Systemic candidiasis and cryptococcal infections (including meningitis): Orally 400 mg initially daily then 200 mg daily and continue treatment according to response.

Prevention of fungal infections in immunocompromised patients: 50 mg orally daily. Prevention of relapse of cryptococcal meningitis, AIDS patients after completion of primary therapy: 100 mg-200 mg orally daily.

Children: As with similar infections in adults, the duration of treatment is based on the clinical and mycological response. Mucosal candidiasis: 3 mg/kg daily. A loading dose of 6 mg/kg may be used on the first day to achieve steady state levels more rapidly. Systemic candidiasis and cryptococcal infection: 6-12 mg/kg daily, depending on the severity of the disease. Prevention of fungal infections in immunocompromised patients considered at risk as a consequence of neutropenia following cytotoxic chemotherapy or radiotherapy: 3 - 12 mg/kg daily, depending on the extent and duration of the induced neutropenia (see adult dosing). For children with impaired renal function the daily dose should be reduced in accordance with the guidelines given for adults.

SIDE-EFFECTS

Fluconazole is generally well tolerated. The commonest side-effects associated with Fluconazole are symptoms associated with the gastro-intestinal tract; these include nausea, abdominal discomfort, diarrhea and atulence. Other adverse events such as rash are rarely encountered (incidence less than 1%). In rare cases, as with other azoles, anaphylaxis has been reported.

CONTRAINDICATIONS

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

PRECAUTIONS

Renal impairment, pregnancy and raised liver enzymes. Fluconazole is found in breast milk in same concentration similar to plasma, hence its use in nursing mothers is not recommended.

OVERDOSE

If there is any overdose, supportive measure and gastric lavage should be instituted according to the patient's clinical conditions. As Fluconazole is excreted largely in urine volume diuresis would probably increase elimination rate. A three-hour session of haemodialysis decreases plasma levels approximately 50%.

DRUG INTERACTION

Fluconazole increases the prothrombin time after warfarin administration in healthy males. It has been shown to prolong the serum half life of concomitantly administered oral sulphonylureas. Co-administration of multiple dose-hydrochlorothiazide to healthy volunteers receiving Fluconazole increased plasma concentrations of Fluconazole by 40%. Concomitant administration of Fluconazole and phenytoin may increase the level of phenytoin to a clinically significant degree. Concomitant administration of Fluconazole and rifampicin decreases availability of Fluconazole. In females, Fluconazole is unlikely to have an effect on the efficacy of combined oral contraceptive pill. Interaction studies have shown that when oral uconazole is co-administered with food, cimetidine, antacids or following total bone irradiation for bone marrow transplantation no clinically significant impairment of Fluconazole absorption occurs. Concomitant administration of Fluconazole and Theophylline decreases the availability of the later.

PHARMACEUTICAL PRECAUTION

Keep capsule from light & moisture. Keep Powder for Suspension not above 30 °C temperature, away from light & moisture. Keep out of reach of children.

PACKAGING

Flucoder® 50 Capsule	:	Box containing 3 strips of 10 capsules each. Each capsule contains Fluconazole USP 50 mg.
Flucoder® 150 Capsule	:	Box containing 1 strip of 10 capsules. Each capsule contains Fluconazole USP 150 mg.
Flucoder® 200 Capsule	:	Box containing 1 strip of 10 capsules. Each capsule contains Fluconazole USP 200 mg.
Flucoder® Powder for Suspension	:	Dry powder in amber glass bottle for reconstitution to 35 mL of suspension. After reconstitution, each 5 mL contains Fluconazole USP 50 mg.

SK+F

Manufactured by
ESKAYEF PHARMACEUTICALS LTD.
GAZIPUR, BANGLADESH

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