

Flugard

Fluconazole USP

Capsule

50 mg & 150 mg

Composition

Flugard 50 mg capsule: Each capsule contains Fluconazole USP 50 mg.

Flugard 150 mg capsule: Each capsule contains Fluconazole USP 150 mg.

Description

Fluconazole is a triazole antifungal drug that inhibits cytochrome P-450 dependent enzymes resulting in blockade of ergosterol synthesis. Fluconazole is well absorbed following oral administration and is widely distributed and achieves concentration in joint fluid, saliva, sputum, vaginal fluid and peritoneal fluid 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 candidal infection. Cryptococcosis, cryptococcal meningitis and infections of other sites (pulmonary and cutaneous). For prevention of fungal infections in immunocompromised patients e.g. neutropenic cancer patients.

Dosage and Administration

Adult: Acute and recurrent vaginal candidiasis and candidal balanitis: Orally a single dose 150 mg, Mucosal candidiasis (except vaginal): Orally 50 mg daily (100 mg daily in a single dose in usually difficult infection) for 7-14 days. Oropharyngeal candidiasis for maximum 14 days, in atrophic oral candidiasis with denture for 14 days, in oesophagitis and candiduria for 14-30 days. Tinea pedis, corporis, cruris, pityriasis 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 50-400 mg daily adjusted according to risk. Prevention of relapse of cryptococcal meningitis, AIDS patients after completion of primary therapy: 100 mg- 200 mg orally daily.

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, diarrhoea and flatulence. Other adverse events such as rash are rarely encountered (incidence less than 1%). Less frequently dyspepsia, vomiting, taste disturbance, hepatic disorders, angioedema, dizziness, pruritus may occur.

Contraindications

Fluconazole should not be used in patients with known hypersensitivity to fluconazole or to relatedazole compounds.

Precautions

Renal impairment, pregnancy and raised liver enzymes. Discontinue if signs or symptoms of hepatic disease (risk of hepatic necrosis). 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 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 sulphonyl ureas. Co-administration of multiple dose-hydrochlorothiazide to healthy volunteers receiving fluconazole increased plasma concentration 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 decrease the availability of fluconazole. Concomitant administration of fluconazole and theophylline decrease the availability of the later. Fluconazole increases plasma concentration of celecoxib (dose should be reduced to halve), zidovudine (increased risk of toxicity), midazolam (prolonged sedative effect), bosentan (avoid concomitant use) and tacrolimus. Effect of acenocounazole is enhanced by fluconazole.

Pharmaceutical Precautions

Store at temperature not exceeding 30°C. Store in a cool and dry place, keep away from light. Keep out of reach of children.

How Supplied

Flugard 50 mg capsule: Box containing 30 capsules in Alu-Alu blister pack.

Flugard 150 mg capsule: Box containing 30 capsules in Alu-PVDC blister pack.



Manufactured by
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