

FLUCOAIM 150mg (Fluconazole) Tablet / Capsule

فلوکوایم
(فلوکونازول)

DESCRIPTION:

FLUCOAIM (Fluconazole), the first of a new subclass of synthetic triazole antifungal agents, is available as a 150mg tablet for oral administration.

COMPOSITION:

Each Tablet contains:

Fluconazole (Aims Specification).....150mg

Each Capsule, contains:

Fluconazole (Aims Specification).....150mg

CLINICAL PHARMACOLOGY:

Mode of Action

Fluconazole inhibits of fungal cytochrome P450 enzyme 14-demethylase. Mammalian Demethylase activity is much less sensitive to fluconazole than fungal demethylase. This inhibition prevents the Fluconazole inhibits of fungal cytochrome P450 enzyme 14. Pharmacokinetics. Fluconazole is well absorbed after oral administration. The bioavailability of orally administered fluconazole is over 90%. Mean peak plasma concentrations of 6.72 ug/ml have been reported in healthy subjects following a 400mg oral dose. Peak concentrations are reached in 1 to 2 hrs of oral administration. Steady state concentrations are reached within 6 to 10 days following oral doses of 50 to 400mg given once daily. Plasma protein binding is low (11 to 12%). Following either single or multiple oral doses for up to 14 days, Fluconazole is widely distributed into all body fluids and the apparent volume of distribution is close to that of the total body water. Concentration in joint fluid, breast milk, saliva, sputum, vaginal fluids, peritoneal fluids are those achieved in plasma. Concentration in CSF range from 50 to 90% if okasma. Concentration even in the absence of meningeal inflammation.

Fluconazole is cleared primarily by renal excretion, with approximately 80% of the drug is excreted as unchanged in the urine and about 11% of the drug is eliminated as metabolites. The elimination half life is about 30 hours and is increased in patients with impaired renal function. The pharmacokinetics of fluconazole is markedly affected by reduction-in renal function, so the dose of fluconazole may need to be reduced in patients with impaired renal function, Fluconazole is removed by dialysis.

Microbiology

Fluconazole is active against.

Blastomyces dermatitidis.

Candida spp. (Except C. Krusie)

Coccidioides immitis.

Cryptococcus neoformans

Epidermophyton spp.

Histoplasma capsulatum

Microsporium spp.

Trichophyton spp.

THERAPEUTIC INDICATIONS:

Fluconazole is indicated for the treatment of

1. Vaginal candidiasis (Vaginal yeast infections due to Candida)

2. Oropharyngeal and esophageal candidiasis. Fluconazole is also effective for the treatment of Candida

urinary tract infections, peritonitis, and systemic Candida infections including candidemia, disseminated candidiasis and pneumonia.

3. Dermatomycosis i.e. Tinea pedis, Tinea corporis, Tinea cruris, Tinea versicolor

4. Cryptococcosis including cryptococcal meningitis.

5. Tinea unguium.

Fluconazole is also indicated to decrease the incidence of candidiasis in patients undergoing bone marrow transplantation who receive cytotoxic chemotherapy and/or radiation therapy.

Contra-Indications:

Fluconazole is contra-indicated for patients who have shown hypersensitivity to fluconazole and should be prescribed with caution to patients with hypersensitivity to other azoles. Co-administration of fluconazole with cisapride or terfenadine is contra-indicated because of reports of cardiac events.

UNDESIRABLE EFFECTS:

Fluconazole is generally well tolerated. The most common effects include

Gastrointestinal effects: Abdominal pain, nausea, vomiting, flatulence and taste disturbance.

CNS effects: Headache and dizziness.

Hepatic effects: Hepatic toxicity including elevated liver enzymes (Alkaline Phosphatase, SGPT, SGOT)

and increased bilirubin level.

Skin/Allergic reactions: Rashes, alopecia, Stevens-Johnson syndrome and toxic epidermal necrolysis.

Body as a whole: Anaphylaxis and angioedema.

Metabolic effects: Hypokalemia and hyperlipidemia.

DRUG INTERACTIONS:

- Hydrochlorothiazide increases the plasma concentrations of fluconazole.
- Cimetidine decreases Fluconazole the plasma concentrations of fluconazole.
- Fluconazole reduces the metabolism of oral hypoglycemic (Tolbutamide, glyburide and glipizide) and increases the plasma concentration of these agents.
- Prothrombin time may be increased in patients receiving concomitant fluconazole and coumarin-type anticoagulants. In post marketing experience as with other azole antifungals, bleeding events (Bruising, epistaxis, gastrointestinal bleeding, hematuria and melena) have been reported in association increase prothrombin in the patients receiving fluconazole concurrently with warfarin.
- Fluconazole increases the plasma concentrations of Phenytoin.
- Fluconazole may significantly increase cyclosporin levels in renal transplant patients with or without renal impairment.
- Rifampicin enhances the metabolism of concurrently administered fluconazole.
- Fluconazole increases the serum concentrations of theophylline.
- There have been reports of cardiac events, including torsade de pointes in patients to whom fluconazole astemizole or other drugs.
- The use of fluconazole in patients concurrently taking metabolized by the cytochrome P450 system may be associated with elevations in serum levels of these drugs.
- Following oral administration of midazolam, fluconazole resulted in substantial increase in midazolam concentrations and psychomotor effects.

WARNINGS AND PRECAUTIONS:

Pregnancy

There are no adequate and well controlled studies in pregnant women. Fluconazole should be used in-pregnancy only if the potential benefits justifies the possible risk to the fetus.

Nursing Mothers

Fluconazole is secreted in human milk at concentrations similar to plasma, therefore, the use of fluconazole in nursing mothers is not recommended.

DOSAGE AND ADMINISTRATION:

DOSAGE SCHEDULE	
Vaginal candidiasis	150mg as a single oral dose.
Dermal infections including Tinea pedis, corporis, cruris and Candida infections	150mg once weekly for 2 to 4 weeks but Tinea pedis may require treatment for up to 6 weeks.
Tinea Versicolor	300mg once weekly for 2 weeks.
Tinea unguium	150mg once weekly, treatment should be continued until infected nail is replaced.

Presentation:

Flucoaim 150mg tablet is available in a blister pack of one tablet.

Flucoaim 150mg Capsule is available in a blister pack of one capsule.

PRECAUTION:

- Use as prescribed by the physician.
- Keep out of the reach of children.
- Store at room temperature.
- Protect from direct sunlight, heat & moisture.

ہدایات:

دوا کو اکثر کی ہدایت کے مطابق استعمال کریں۔

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Manufactured by:
Aims Pharmaceuticals
Plot # 291, Industrial Triangle
Kahuta Road, Islamabad - Pakistan.
www.aimspharmaceuticals.com

