Omastin®

Capsule / Suspension

Description

Omastin (Fluconazole) is a triazole antifungal agent. It is a potent and selective inhibitor of fungal cytochrome P450 dependent enzymes necessary for the synthesis of ergosterol.

Indications

- Vaginal Candidiasis
- Oropharyngeal Candidiasis
- Oesophageal Candidiasis
- Systemic Candidiasis and Cryptococcal infection
- Tinea corporis / Tinea cruris / Tinea pedis / Other Tinea
- Kerion
- Pityriasis versicolor
- Onychomycosis

Other indications

- Fungal urinary tract infections
- Disseminated candidiasis
- Prophylaxis for fungal infection in neutropenic cancer patients.
- Acute treatment of other systemic fungal infections such as coccidioidomycosis and histoplasmosis

Dosage and Administration

Recommended dosages are given below, and this regimen is recommended from early infection to severe infections.

® 150 mg as a single dose or 200 mg in 1st day followed by 100 mg daily for 14 days

® 200 mg in 1st day followed by 100 mg daily for 14-30 days.

® 400 mg in 1st day followed by 200 mg daily for 28 days or longer based on clinical response

® 150 mg weekly for 4-6 weeks

® 50 mg daily for 20 days

® 400 mg as a single dose

® 150 mg weekly for 12 months.

Child over 1 year

- In Superficial Candidiasis : 1-2 mg/kg daily
- In Systemic Candidiasis and Cryptococcal infection : 3-6 mg/kg daily

In serious life threatening infections up to 12 mg/kg daily has been given to children aged 5 -13 years (Maximum 400 mg daily)

Age	**Average Weight**	**Dose/Day**
1 year	9 kg	½ spoonful
1-2 years	12 kg	1 spoonful
2-3 years	14 kg	1½ spoonful
3-4 years	16 kg	2 spoonful
4-6 years	20 kg	2½ spoonful

The daily dose of Omastin 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. An inadequate period of treatment may lead to recurrence of active infection. Immuno-compromised patients usually require maintenance therapy to prevent relapse.

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 of patients with renal impairment, normal doses should be given on days 1 and 2 of treatment and thereafter the dosage intervals should be modified as follows :

Creatinine Clearance (ml/min)	**Dosage Interval** (hours)
> 41	24
21 - 40	48
10 - 20	72
Patients receiving regular dialysis	One dose after every dialysis session

Paediatric use

Few formal studies have been done in children. Doses of 3-6 mg/kg daily have been used without serious adverse reactions being reported. Renal clearance in children may be proportionately more rapid than in adults and doses up to 12 mg/kg is recommended.

Effects on liver

For the liver as a potential target organ, the available data indicate that, Fluconazole is not predictable hepatotoxic drug in man. In man, including those with existing hypercholesterolaemia, serum cholesterol is not adversely affected by Fluconazole.

Contraindication

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

Drug Interactions

Fluconazole acts by inhibiting fungal cytochrome P450 enzymes. It is much less active against mammalian P450 enzymes, still potential exists for interaction with drugs that are metabolized by P450.

- Cyclosporin

  Some data suggest that Fluconazole increases cyclosporin levels.
- Phenytoin

  Fluconazole significantly increases Phenytoin levels.
- Anticoagulants

  Fluconazole has shown to prolong prothrombin time in subjects receiving Warfarin.
- Oral hypoglycaemics

  Fluconazole has been shown to prolong the serum half life of concomitantly administered Tolbutamide. However no adverse effect on serum glucose levels was seen.

- Rifampicin
  Decreases levels of Fluconazole.
- Oral contraceptives
  No clinically significant interactions have been seen.

Side Effects

Therapy with Fluconazole is well tolerated. In 4000 patients receiving Fluconazole for various indications and for durations of 7 days or more, the incidence of side effects were 16% . Only 1.5% of subjects required discontinuation of medication. The most common adverse events were related to the gastrointestinal system : nausea (3.7%), abdominal pain (1.17%), vomiting (1.7%) and diarrhoea (1.5%). Headache (1.9%) and skin rash (1.8%) were also seen. It should be noted that approximately one third of this group were patients with acquired immunodeficiency syndrome (AIDS) and severe systemic disorders. Therefore the data may not be applicable to patients receiving Fluconazole for the treatment of superficial mycoses.

Use in Special Populations

Pregnancy : Adverse foetal effects have been seen in animals only at doses ranging from 80 mg/kg to 320 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 foetus.

Lactation : Fluconazole is secreted in human milk at concentrations similar to plasma. Therefore, the use of fluconazole in nursing mother is not recommended.

Commercial Packs

Omastin® 50 Capsule : Box containing 5 aluminium strips of 10 capsules, each capsule contains Fluconazole INN 50 mg.

Omastin® 150 Capsule : Box containing 2 blister strips of 10 capsules, each capsule contains Fluconazole INN 150 mg.

Omastin® Suspension : Dry powder in glass bottle for reconstitution into 35 ml of suspension. After reconstitution, each 5 ml contains Fluconazole INN 50 mg.