

Iluca

Fluconazole

Composition

Iluca 50 Tablet : Each capsule contains Fluconazole USP 50 mg.

Iluca 150 Tablet : Each capsule contains Fluconazole USP 150 mg.

Mode of Action

Fluconazole is a highly selective inhibitor of fungal cytochrome P-450 sterol C-4 alpha-demethylation. The subsequent loss of normal sterols correlates with the accumulation of 14 alpha-methyl sterols in fungi and may be responsible for the fungistatic activity of fluconazole.

Pharmacokinetics

The bioavailability of orally administered fluconazole is over 90%. Peak plasma concentration occur between 1 and 2 hours with a terminal plasma elimination half-life of approximately 30 hours (range :20-50 hours) after oral administration.

Indication

Iluca is indicated for the treatment of:

1. Vaginal Candidiasis & Candidial balanitis.
2. Oropharyngeal and esophageal candidiasis.
3. Systemic Candida Infections : In open noncomparative studies of relatively small numbers of patients, fluconazole was also effective for the treatment of Candida urinary tract infections, peritonitis and systemic Candida infections including candidemia, disseminated candidiasis and pneumonia.
4. Cryptococcal meningitis.
5. Tinea pedis, corporis, cruris, versicolor and dermal candidiasis.
6. Kerion, Pityriasis versicolor & Onychomycosis.
7. Prophylaxis in bone marrow transplantation: Fluconazole is also indicated to decrease the incidence of candidiasis in patients undergoing bone marrow transplantation who receive cytotoxic chemotherapy and/or radiation therapy.

Dosage and Administration

Adults : **Vaginal candidiasis & Candidial balanitis**: 150 mg as a single oral dose.

Oropharyngeal Candidiasis : 200 mg on the first day, followed by 100 mg once daily for 14 days.

Esophageal Candidiasis : 200 mg on the first day, followed by 100 mg once daily. Doses up to 400 mg/day may be used, based on medical judgement of the patient's response to therapy. Patients with esophageal candidiasis should be treated for a minimum of three weeks and for at least two weeks following resolution of symptoms;

Systemic Candida Infections & Cryptococcal Meningitis : For systemic Candida infections including candidemia, disseminated candidiasis, and pneumonia, & Cryptococcal Meningitis the recommended dosage is 400 mg on the first day, followed by 200 mg once daily and if necessary , dosage increase to 400 mg once daily- treatment continued according to medical judgment of the patient's response. Suppression dosage of relapse of cryptococcal meningitis in patients with AIDS is 200 mg once daily.

Tinea pedis, corporis, cruris, versicolor and dermal candidiasis : 50 mg daily for 2-4 weeks (for upto 6 weeks in tinea pedis) ; maximum duration of treatment 6 weeks.

Kerion : 50 mg daily for 20 days.

Pityriasis versicolor : 400 mg as a single dose.

Onychomycosis : 150 mg weekly for 12 month.

Prophylaxis in Patients Undergoing Bone Marrow Transplantation : 400 mg once daily. Patients who are anticipated to have severe granulocytopenia (less than 500 neutrophils per cu mm) should start fluconazole prophylaxis several days before the anticipated onset of neutropenia, and continue for 7 days after the neutrophil count rises above 1000 cells per cu mm.

Child over 1 year: For superficial candidal infection, 1-2 mg /kg; systemic

candidiasis and cryptococcal infections, 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 -max. 400 mg daily).

Contraindication

The product must not be taken in case of known hypersensitivity to fluconazole, an ingredient of the product or other azoles. Fluconazole must not be used in doses of 400 mg or more a day at the same time as terfenadine (a particular agent for allergic symptoms). Care is necessary in patients with renal or hepatic dysfunction.

Use in pregnancy and lactation

Since there is inadequate clinical experience, ILUCA should not be taken during pregnancy except for life-threatening conditions about which only your doctor can decide.

Iluca must not be taken during lactation.

Interactions

The action of **Iluca** may be changed if it is taken at the same time as a number of other medicines, or it may change their effects, examples being coumarin derivatives, sulphonylureas, hydrochlorothiazide, phenytoin, oral contraceptives, rifampicin, cyclosporin, theophylline, astemizole, zidovudine, midazolam,

triazolam, rifabulin and tacrolimus. Simultaneous use of terfenadine and cisapride may lead to cardiac arrhythmias through increasing the levels of these substances in the blood.

Overdosage

In one case of an extremely high overdosage there were transient behavioural disturbances with delusions. With suitable treatment in hospital the condition normalized within 48 hours. An unintentional overdosage should be reported to doctor without delay. If an overdose is taken, symptomatic treatment with supportive measures is indicated, if necessary gastric lavage. Since fluconazole undergoes renal elimination, forced diuresis increases the rate of elimination. A three hour haemodialysis reduces the plasma concentration by about 50%.

Adverse effects : Like all active substances, this medicine may also have unpleasant effect in some people. The following side effects have been reported.

Gastrointestinal tract : nausea, abdominal pain, diarrhoea, flatulence.

Central nervous system : headache.

Skin : rashes, including diffuse rashes accompanied by changes in the blood picture and itching.

Storage : Store in dry place below 25° C. Medicines should be kept out of the reach of Children.

Presentation

Iluca 50 Capsule : Each box contains 4 x 5's capsules in alu-alu blister pack.

Iluca 150 Capsule : Each box contains 4 x 3's capsules in alu-alu blister pack.

Manufactured by:



The IBN SINA Pharmaceutical Industry Ltd.
Shafipur, Gazipur, Bangladesh