ILUCA

FLUCONAZOLE USP

Compositions:
Iluca 50 capsule: Each capsule contains Fluconazole USP 50 mg. Iluca 150 capsule: Each capsule contains Fluconazole USP 150 mg. Iluca 35 ml powder for suspension: Each 5 ml suspension contains Fluconazole USP 50 mg.

Pharmacology:
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. 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.

Dosage And Administration:
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: l50 ing 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; for 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).

Contraindications:
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.

Warning And Precaution:
Fluconazole should be administered with caution to patients with liver dysfunction. Fluconazole has been associated with rare cases of serious hepatic toxicity including fatalities, primarily in patients with serious underlying medical conditions. In cases of fluconazole-associated hepatotoxicity, no obvious relationship to total daily dose, duration of therapy, sex or age of patient has been observed. Fluconazole hepatotoxicity has usually been

reversible on discontinuation of therapy. Patients who develop abnormal liver function tests during fluconazole therapy must be monitored closely for the development of more serious hepatic injury. The patient should be informed of suggestive symptoms of serious hepatic effect (important asthenia, anorexia, persistent nausea, vomiting and jaundice). Treatment of fluconazole should be immediately discontinued and the patient should consult a physician.

Side 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 accompained by changes in the blood picture and itching.

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.

Drug Interaction:
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, hydrochiorothiazide, phenytoin, oral eontraceptives, rifampicin, cyclosporin, theophyline, astemizole, zidovudine, midazolam, triazolam, rifabulin and tacrolimus. Simultaneous use of terfenadine and cisapride may lead to cardiac arrhythrnias 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%.

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

Packing:
Iluca 50 Capsule: Each box contains 2 x 10s capsules in Alu-Alu blister pack. Iluca 150 Capsule: Each box contains 3x4 capsules in Alu-Alu blister pack. Iluca 35/50/100 ml suspension: Each bottle contains 35 ml powder for suspension.

Manufactured By:
The IBN SINA Pharmaceutical Industry PLC.
Shafipur, Gazipur, Bangladesh.