

Flutinex™

Fluconazole

COMPOSITION:

Flutinex™ 50 Capsule: Each capsule contains fluconazole BP 50 mg.

Flutinex™ 150 Capsule: Each capsule contains fluconazole BP 150 mg.

Flutinex™ Powder for Suspension: Each 5 ml reconstituted suspension contains Fluconazole BP 50 mg.

PHARMACOLOGY:

Fluconazole Inhibits fungal cytochrome P450 3A dependent enzyme lanosterol 14- α -demethylase. As a result decreases ergosterol synthesis and inhibits cell membrane formation

INDICATIONS:

Flutinex™ is used for the treatment of:

- Vaginal candidiasis (acute or recurrent)
- Mucosal candidiasis including oropharyngeal, oesophageal, non-invasive bronchopulmonary infection, mucocutaneous
- Tinea pedis, tinea corporis, tinea cruris, tinea versicolor and dermal candida infections. it is not indicated for nail infection.
- Systemic candidiasis including candidaemia, disseminated candidiasis and other form of invasive candidial infections, including infections peritoneum, endocardium, pulmonary and urinary tract
- Cryptococcosis, including cryptococcal meningitis, Normal hosts & patients with AIDS, organ transplants or other cause of cryptococcal disease in patients with AIDS

DOSAGE AND ADMINISTRATION:

Route of administration: Flutinex™ capsule and PFS should be administered orally according to dosage guidelines.

- Vaginal candidiasis: 150 mg once daily
- Mucosal candidiasis: 50 mg once daily for 7-10 days (except in severe infections: 100 mg daily)
- Cryptococcal infections: 400 mg on first day; then 200 mg to 400 mg daily for 6-8 weeks

CONTRAINDICATIONS:

Patient with history of hypersensitivity to fluconazole or any azole group and liver disease.

WARNINGS & PRECAUTIONS:

Since Fluconazole is primarily excreted by the kidneys, dose must be adjusted on renal impairment. Fluconazole is potentially hepatotoxic. Although no clear guidance is available for the use of Fluconazole in liver disease, but it seems prudent to closely monitor liver blood tests in these patients.

SIDE-EFFECTS:

The is generally well tolerated.

Common side effects: The most frequent side effects observed are gastrointestinal effects such as upset stomach.

Rare side effects: Anaphylaxis has been reported.

USAGE IN PREGNANCY AND LACTATION:

Use in pregnancy: There are limited data on the use of Fluconazole in pregnant woman. Fluconazole should be used in pregnancy only when the benefit clearly out of the risk. As it appears in human breast milk.

During lactation: Fluconazole should not be given during lactation.

DRUG INTERACTIONS:

Rifampicin reduces plasma concentration of Fluconazole. Effect of nicoumalone, phenyton and warfarin is enhanced and plasma concentrations of sulphonylureas and theophylline are possibly increased by fluconazole.

OVERDOSE:

Overdose of Fluconazole can cause hallucination, gastric lavage, ptosis & urinary incontinence.

STORAGE:

Protect from light exposure. Store in cool and dry place at a temperature not exceeding 30° C. Keep out of the reach of children.

PACKING:

Flutinex™ 50 Capsule: Each box contains 30 capsule in blister strip.

Flutinex™ 150 Capsule: Each box contains 30 capsule in blister strip.

Flutinex™ Powder for Suspension: Bottle containing dry powder for preparation of 35 ml suspension.

Manufactured by:

Organic Health Care Ltd.

Gilarchala, 7 Kewa Mouza, Sreepur, Gazipur, Bangladesh.

