

FLUFUNG

(Fluconazole)

150mg Capsule
50mg/5ml Dry Suspension

کپسول اور سیرپ

فلوفنگ
فلوکونازول

DESCRIPTION:

Flufung being new subclass of synthetic triazole antifungal agents, is available as capsule for oral administration, as a powder for oral suspension. The empirical formula of **FLUFUNG** is $C_{13}H_{12}F_2N_6O$

COMPOSITION:

FLUFUNG 150mg Capsule

Each capsule contains:

Fluconazole150mg

FLUFUNG 50mg/5ml Dry Suspension

Each 5ml contains:

Fluconazole50mg

CLINICAL PHARMACOLOGY:

Following oral dosing, fluconazole is almost completely absorbed within two hours. Bio availability is not significantly affected by the absence of stomach acid. Concentrations measured in the urine, tears and skin are approximately 10 times the plasma concentration, whereas saliva, sputum and vaginal fluid concentrations are approximately equal to the plasma concentration, following a standard dose range of between 100mg and 400 mg per day. The elimination half-life of fluconazole follows zero order and only 10% of elimination is due to metabolism, the remainder being excreted in urine and sweat. Patients with impaired renal function will be at risk of over dose.

MECHANISM OF ACTION:

Fluconazole inhibits the fungal cytochrome P450 enzyme 14α -demethylase. Mammalian demethylase activity is much less sensitive to fluconazole than fungal demethylase. This inhibition prevents the conversion of lanosterol to ergosterol, an essential component of the fungal cytoplasmic membrane and subsequent accumulation of 14α -methyl sterols. Fluconazole is primarily fungi static; however, it may be fungicidal against certain organisms in a dose-dependent manner, specifically cryptococcus.

INDICATIONS:

FLUFUNG (fluconazole) is indicated for the treatment of:

1. Vaginal candidiasis (vaginal yeast infections due to candida).
2. Oropharyngeal and esophageal candidiasis. In open non comparative studies of relatively small numbers of patients, **Flufung** was also effective for the treatment of candida urinary tract infections, peritonitis and systemic candida infections including candidemia, disseminated candidiasis and pneumonia.
3. Cryptococcal meningitis.

DOSAGE AND ADMINISTRATION:

Adults:

Single Dose Vaginal candidiasis:

The recommended dosage of **FLUFUNG** for vaginal candidiasis is 150 mg as a single oral dose.

Dermal Infections The recommended dosage of **FLUFUNG** for Dermal Infections is 150mg once weekly for 2 to 4 weeks for tinea versicolor. The recommended dosage of **FLUFUNG** for Tinea versicolor 150mg once weekly until infection is replaced.

CONTRAINDICATIONS:

Fluconazole is contraindicated in patients who:

- Drink alcohol
- have known hypersensitivity to other azole medicines such as ketoconazole;
- are taking terfenadine, if 400 mg per day multidose of fluconazole is administered;
- concomitant administration of fluconazole and quinidine, especially when fluconazole is administered in high dosages;
- Take SSRIs such as fluoxetine or sertraline.

WARNINGS AND PRECAUTIONS:

(Fluconazole) is contraindicated in patients who have shown hypersensitivity to fluconazole or to any of its excipients. There is no information regarding cross hypersensitivity. **Hepatic injury: FLUFUNG** should be administered with caution to patients with liver dysfunction. **FLUFUNG** has been associated with rare cases of serious hepatic toxicity, including fatalities primarily in patients with serious underlying medical conditions.

DRUG INTERACTIONS:

Fluconazole is an inhibitor of the human cytochrome P450 system, particularly the isozyme CYP2C19 (CYP3A4 and CYP2C9 to lesser extent) In theory, therefore, fluconazole decreases the metabolism and increases the concentration of any drug metabolised by these enzymes. In addition, its potential effect on QT interval increases the risk of cardiac arrhythmia if used concurrently with other drugs that prolong the QT interval. Berberine has been shown to exert synergistic effects with fluconazole even in drug-resistant candida albicans infections. Fluconazole may increase the serum concentration of Erythromycin (Risk X: avoid combination)

POSSIBLE SIDE EFFECTS:

Adverse drug reactions associated with fluconazole therapy include:

- Common ($\geq 1\%$ of patients): rash, headache, dizziness, nausea, vomiting, abdominal pain, diarrhea and/or elevated liver enzymes
- Infrequent (0.1–1% of patients): anorexia, fatigue, constipation
- Rare ($<0.1\%$ of patients): oliguria, hypokalaemia, paraesthesia, seizures, alopecia, Stevens–Johnson syndrome, thrombocytopenia, other blood dyscrasias, serious hepatotoxicity including liver failure, anaphylactic/anaphylactoid reactions
- Very rare: prolonged QT interval, torsades de pointes
- FDA is now saying treatment with chronic, high doses of fluconazole during the first trimester of pregnancy may be associated with a rare and distinct set of birth defects in infants.

STORAGE & INSTRUCTIONS:

Keep out of the reach of children & store below 30°C. Protect from sunlight & moisture Improper storage may deteriorate the medicine. Do not use this medicine after the expiry date which is stated on the blister.

PRESENTATION:

FLUFUNG 150mg capsule is available in blister pack of 1's.

FLUFUNG 50mg/5ml dry suspension is available in pack of 35ml.

Manufactured by :



PHARMA LORD | 12km, Lahore
(PVT.) LIMITED | Road, Layyah.
Pakistan
www.pharma-lord.com

کپسول اور سیرپ
فلوفنگ

فلوконаزول

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: بچوں کی پہنچ سے دور رکھیں۔

دوا کو دھوپ، گرمی اور نمی سے محفوظ رکھیں۔

سے کم درجہ حرارت پر رکھیں۔