

Diflu

Fluconazole USP

Composition :

Diflu-50 Capsule: Each capsule contains Fluconazole USP 50 mg.

Diflu-150 Capsule: Each capsule contains Fluconazole USP 150 mg.

Diflu-200 Capsule: Each capsule contains Fluconazole USP 200 mg.

Diflu Powder for Suspension : When prepared, each 5 ml contains Fluconazole USP 50 mg.

Pharmacology :

Diflu (Fluconazole) is the first of a new subclass of synthetic triazole antifungal agent which acts by inhibition of the ergosterol component of the fungal cell membrane. It is active against a broad spectrum of fungal pathogens and is available for oral use.

Indications :

It is indicated in the treatment of vaginal candidiasis, oropharyngeal & oesophageal candidiasis, candidal urinary tract infection, peritonitis, systemic candidiasis and cryptococcal meningitis.

Dosage and Administration :

The daily dose of DIFLU should be based on the nature and severity of the fungal infection. Most cases of the fungal infections require multiple dose therapy. Treatment should be continued until clinical parameters of laboratory tests indicate that active fungal infection has subsided. An inadequate period of treatment may lead to recurrence of active infection. Immunocompromised patients usually require maintenance therapy to prevent relapse.

Infections	Recommended dosage
Adults:	
Vaginal candidiasis	150 mg as a single dose
Oropharyngeal candidiasis	200 mg on the 1st day followed by 100 mg daily for 14 days
Oesophageal candidiasis	200 mg on the 1st day followed by 100 mg daily for 14-30 days
Systemic candidiasis & Cryptococcal infection	400 mg on the 1st day followed by 200 mg daily for 28 days or longer based on clinical response
Tinea corporis/ tinea cruris/ tinea pedis/ other tinea kerion	50 mg daily for 2-4 weeks (for up to 6 weeks in tinea pedis)
Prevention of fungal infections in immunocompromised patients	50-400 mg daily adjusted according to risk

Neonates :	
Oesophageal candidiasis	3 mg/Kg every 72 hours up to 2 weeks old 3 mg/Kg every 48 hours up to 2-4 weeks old
Systemic candidiasis & cryptococcal infection	6-12 mg/kg every 72 hours up to 2 weeks old 6-12 mg/kg every 48 hours up to 2-4 weeks old
Prevention of fungal infections in immunocompromised patients	3-12 mg/kg every 72 hours up to 2 weeks old 3-12 mg/kg every 48 hours up to 2-4 weeks old

Children above 1 year :	
Superficial candidiasis	1-2 mg/kg body weight daily
Systemic candidiasis & cryptococcal infection	3-6 mg/Kg body weight daily

In serious life threatening infections up to 12 mg/Kg body weight daily may be given to children aged 5-13 years (maximum 400 mg daily)

Age	Average body weight	Dose/Day
1 year	9 Kg	$\frac{1}{2}$ measuring spoonful
1-2 years	12 Kg	1 measuring spoonful
2-3 years	14 Kg	$1\frac{1}{2}$ measuring spoonfuls
3-4 years	16 Kg	2 measuring spoonfuls
4-6 years	20 Kg	$2\frac{1}{2}$ measuring spoonfuls

Contraindications :

It is contraindicated to patients hypersensitive to this drug and in advanced liver disease and in nursing mother.

Precautions :

Caution should be taken in renal impairment, pregnancy and breast-feeding and the raised liver enzymes.

Side Effects :

Therapy with Fluconazole is well tolerated. The common adverse effects are nausea, abdominal pain, vomiting, diarrhoea, headache and skin rash.

Drug Interactions :

Rifampicin reduces plasma concentration of Fluconazole. Fluconazole enhances the effect of nicoumalone, warfarin and phenytoin. It also increases the plasma concentration of sulphonylureas & theophylline.

Use in pregnancy :

Fluconazole should be used in pregnancy only if the potential benefit justifies the possible risk to the foetus.

Use in lactation :

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

Storage :

Store in a cool and dry place, protect from light, Keep out of the reach of children.

Packing :

Diflu-50 Capsule : Box containing 30's/48's capsules in alu-alu blister pack.

Diflu-150 Capsule : Box containing 12's/24's capsules in alu-alu blister pack.

Diflu-200 Capsule : Box containing 12's/18's/24's/20's/30's/50's capsules in alu-alu blister pack.

Diflu Powder for Suspension : Bottle containing dry powder for preparation of 35 ml/100 ml Suspension.

Manufactured by:

 **ARISTOPHARMA LTD.**
DHAKA-BANGLADESH