

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 |

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| 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 |

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| 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 below 30°C, keep in dry place & protect from light. Keep out of the reach of children.

Packing :

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

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

Diflu®-200 Capsule : Box containing 12's capsules in alu-alu blister pack.

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



Manufactured by:
ARISTOPHARMA LTD.
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