

Orcon[®]

Fluconazole

COMPOSITION:

Orcon[®] 50 Capsule: Each capsule contains Fluconazole USP 50 mg.

Orcon[®] 150 Capsule: Each capsule contains Fluconazole USP 150 mg.

Orcon PFS: Each 5 ml contains Fluconazole USP 50 mg.

PHARMACOLOGY:

Fluconazole is a triazole antifungal drug 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. Following oral administration, absorption is rapid and extensive (>90%). Bioavailability is the same in the fasting and fed states. The bioavailability of Fluconazole is unaffected by gastric pH. The plasma half life is approximately 30h. The plasma protein binding of Fluconazole is low, at 11 % and the drug is widely distributed throughout the body. Most of the dose of Fluconazole is excreted unchanged in the urine, the remainder of the dose being eliminated in the urine as metabolites.

INDICATION:

Orcon[®] is indicated in the treatment of acute or recurrent vaginal candidiasis, mucosal candidiasis (as oropharyngeal candidiasis, oesophagitis, candiduria), systemic candidiasis & cryptococcal infections (including meningitis).

DOSE & ADMINISTRATION:

Adults: Since oral absorption is rapid and almost complete, the daily dose of Orcon[®] is the same for oral & intravenous administration. Oropharyngeal Candidiasis: The recommended dosage of Orcon[®] for oropharyngeal candidiasis is 200 mg on the first day, followed by 100 mg once daily for 7-14 days. Esophageal Candidiasis: The recommended dosage of Orcon[®] for esophageal candidiasis is 200 mg on the first day, followed by 100 mg once daily for 2-3 weeks. Systemic Candidiasis and Cryptococcal Meningitis: 400 mg daily followed by 200 mg once daily. The recommended duration of treatment for initial therapy of cryptococcal meningitis is 10 to 12 weeks. Acute or recurrent vaginal candidiasis: Single dose of 150 mg. Urinary Tract Infections and Peritonitis: 50 to 200 mg once daily. Prophylaxis in Patients Undergoing Bone Marrow Transplantation: 400 mg once daily.

Children: Oropharyngeal Candidiasis: The recommended dosage of Orcon[®] for oropharyngeal candidiasis in children is 6 mg/kg on the first day, followed by 3 mg/kg once daily. Treatment should be administered for at least 2 weeks to decrease the likelihood of relapse. Esophageal

Candidiasis: Recommended dosage of Orcon[®] in children is 6 mg/kg on the first day, followed by 3 mg/kg once daily. Cryptococcal meningitis: Initial therapy should be started with 6 to 12 mg/kg daily. Doses up to 12 mg/kg/day may be used for three weeks and treatment for initial therapy of cryptococcal meningitis is 10 to 12 weeks.

CONTRA-INDICATION:

Fluconazole is contraindicated to patients hypersensitive to this drug and in advanced liver disease.

WARNING AND PRECAUTION:

Caution should be taken in renal impairment, pregnancy and breast feeding and in raised liver enzymes. The use of Fluconazole in lactating mothers is not recommended.

SIDE EFFECTS:

Nausea, abdominal discomfort, diarrhoea and flatulence, occasionally abnormalities of liver enzymes, rarely rash, angioedema and anaphylaxis reported.

USE IN PREGNANCY & LACTATION:

Pregnancy: There are limited data on the use of Fluconazole in pregnant woman. However Fluconazole should be used in pregnancy only when the benefit clearly outweighs the risk.

Lactation: Fluconazole is excreted in breast milk in levels about half of those found in plasma, therefore the drug should be avoided during lactation.

USE IN CHILDREN & ADOLESCENTS:

Efficacy of Fluconazole has not been established in infants less than 6 months of age. It is safe for children over 6 months and adolescents.

DRUG INTERACTION:

Rifampicin reduces plasma concentration of Fluconazole. Effect of nicoumalone, phenytoin and warfarin are enhanced. Plasma concentrations of sulphonylureas & theophylline is possibly increased.

OVERDOSE:

Symptoms of overdose may include hallucination and paranoid behavior.

STORAGE:

Store in a dry and cool place below 30°C temperature and keep away from light and moisture. Keep out of reach of children.

PACKING:

Orcon[®] 50 Capsule: Each box contains 5X10's capsules in blister pack.

Orcon[®] 150 Capsule: Each box contains 1X10's capsules in blister pack.

Orcon PFS: Each bottle contains 35 ml PFS with a 10 ml measuring cup.



Manufactured by

Team Pharmaceuticals Ltd.

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