

ZOLEN

Fluconazole

DESCRIPTION

ZOLEN (Fluconazole) is a broad-spectrum antifungal of Triazole subclass. Fluconazole exerts its antifungal activity by inhibiting the synthesis of ergosterol, a major component of the cell membrane of yeast and fungi. Fluconazole is used for superficial mucosal candidiasis, fungal skin infections, systemic fungal infections and has been tried in blastomycosis, chromoblastomycosis, histoplasmosis, sporotrichosis, and cutaneous leishmaniasis.

COMPOSITION

ZOLEN-50 Capsule: Each capsule contains Fluconazole BP 50 mg.

ZOLEN-150 Capsule: Each capsule contains Fluconazole BP 150 mg.

INDICATION

ZOLEN is indicated for the treatment of the following infections:

- **Vaginal candidiasis and candidal balanitis**
- **Mucosal candidiasis** including oropharyngeal candidiasis, atrophic oral candidiasis associated with dentures
- **Other mucosal infections** (e.g. oesophagitis, candiduria, non-invasive bronchopulmonary infections)
- **Tenia pedis, corporis, cruris, pityriasis versicolor and dermal candidiasis**
- **Systemic/Invasive candidal infections** (including candidaemia and disseminated candidiasis) **and cryptococcal infections** (including meningitis)
- **Prevention of relapse of cryptococcal meningitis in AIDS patients**
- **Prevention of fungal infections in immunocompromised patients**
- **Urinary tract infection and peritonitis**
- **Cutaneous leishmaniasis**

DOSAGE AND ADMINISTRATION

Adults:

Infections	Dose	Treatment Duration
Vaginal candidiasis and candidal balanitis	A single dose of 150 mg.	
Oropharyngeal candidiasis *	50 mg once daily	7-14 days
Atrophic oral candidiasis associated with dentures	50 mg once daily	14 days
Other mucosal infections (e.g. oesophagitis*, candiduria, non-invasive bronchopulmonary infections)	50 mg once daily	14-30 days
Tenia pedis, corporis, cruris, pityriasis versicolor, and dermal candidiasis	50 mg once daily	2-4 weeks (for up to 6 weeks in tenia pedis)
Systemic/Invasive candidal infections (including candidaemia, disseminated candidiasis, pneumonia) and cryptococcal infections (including meningitis)	400 mg initially then 200 mg daily, increased if necessary to 400 mg daily	Treatment continued according to response (at least 6-8 weeks for cryptococcal meningitis)**
Prevention of relapse of cryptococcal meningitis in AIDS patients	100 mg to 200 mg daily	
Prevention of fungal infections in immunocompromised patients	50-400 mg daily adjusted according to risk; 400 mg daily if high risk of systemic infections e.g. following bone-marrow transplantation; commence treatment before anticipated onset of neutropenia and continue for 7 days after neutrophil count in desirable range.	
Urinary tract infection and peritonitis	50-200 mg daily	
Cutaneous leishmaniasis	200 mg daily	6 weeks

* Higher doses are recommended in the USA where an initial dose of Fluconazole 200 mg is followed by 100 mg daily and doses up to 400 mg daily may be used if necessary. ** In the USA 10-12 weeks.

Children (over 4 weeks): Mucosal candidiasis: 6 mg/kg on first day then 3 mg/kg daily. **Systemic/Invasive candidal infections** (including candidaemia and disseminated candidiasis) **and cryptococcal infections** (including meningitis): 12 mg/kg on first day then 6 mg/kg daily. **Prevention of fungal infections in immunocompromised patients:** according to extent and duration of neutropenia, 3-12 mg/kg daily.

Infant (2-4 weeks): Same dose of older children (over 4 weeks) but every 48 hours.

Infant (under 2 weeks) Same dose of older children (over 4 weeks) but every 72 hours.

A maximum dose of 400 mg daily should not be exceeded in children or 12 mg/kg at appropriate intervals in infants.

In renal impairment: Normal loading or initial doses of Fluconazole should be given on the first day of treatment and subsequent doses should be adjusted according to Creatinine Clearance (CC). CC > 50 ml/min: standard dose; CC < 50 ml/min and the patient is not receiving dialysis: ½ the standard dose; patients on regular haemodialysis: standard dose after every dialysis session. No dosage adjustment is needed in single-dose therapy.

CONTRAINDICATION

Fluconazole is contraindicated in known hypersensitivity to Fluconazole or other Azole antifungal agents and in advanced liver disease.

PRECAUTION

Fluconazole should be used with caution in renal or hepatic impairment, arrhythmic conditions.

USE IN PREGNANCY AND LACTATION

Pregnancy: Pregnancy category C. There are no adequate and well controlled studies of Fluconazole in pregnant women. Fluconazole should be considered only if the expected benefit to the mother is greater than any possible risk to the foetus. **Lactation:** Fluconazole is secreted in breast-milk at concentrations similar to plasma. Because of the potential for adverse reactions in nursing infants, decide whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

SIDE EFFECT

Nausea and vomiting, abdominal discomfort, diarrhoea, flatulence, taste disturbance, headache, dizziness, leucopenia, thrombocytopenia, hyperlipidaemia, rash, anaphylaxis, rash, pruritus, toxic epidermal necrolysis, Stevens-Johnson syndrome, alopecia, hypokalemia, QT prolongation, hepatic toxicity.

DRUG INTERACTION

Oral hypoglycemics (Tolbutamide, Glyburide, Glipizide, Nateglinide): plasma concentration of these agents are increased, therefore hypoglycemia may be precipitated. **Coumarin-type anticoagulants (Warfarin):** prothrombin-time may be increased. **Cyclosporine, Phenytoin, Rifabutin, Tacrolimus, Zidovudine:** plasma concentration of these agents are increased. **Benzodiazepines (Midazolam, Triazolam), Nortriptylin:** plasma concentration of these agents are increased. **Astemizole, Cisapride, Terfenadine:** risk of cardiac arrhythmias. **Rifampicin:** reduces plasma concentration of Fluconazole. **Theophylline:** may reduce the clearance of theophylline. **Oral contraceptives:** the efficacy of oral contraceptives may be affected.

STORAGE CONDITION

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

HOW SUPPLIED

ZOLEN-50 Capsule: Each box contains 5 x 10's capsules in blister pack.

ZOLEN-150 Capsule: Each box contains 1 x 10's capsules in blister pack.