Only for the use of Medical Professionals

Canazole

Fluconazole

Description

Canazole is a preparation of Fluconazole, a triazole antifungal drug which is a highly selective inhibitor of fungal cytochrome P-450 dependent enzyme lanosterol 14-a-demethylase. This enzyme functions to convert lanosterol to ergosterol. The subsequent loss of normal sterols correlates with the accumulation of 14-a-methyl sterols in fungi and may be responsible for the fungistatic activity of Fluconazole. Mammalian cell demethylation is much less sensitive to Fluconazole inhibition. It is broad spectrum and well absorbed following oral administration. Gastric pH does not affect on its absorption. Its plasma half life is about 30 hours and elimination half life is about 20-50 hours. It is widely distributed in the body and its plasma concentration is maximum within 1-2 hours after administration.

Indication

Canazole is indicated for acute or recurrent vaginal candidiasis, mucosal candidiasis e.g. oropharyngeal, esophageal, noninvasive bronchopulmonary infections. Dermal tinea infections e.g. tinea pedis, tinea corporis, tinea cruris, tinea versicolor. Systemic candidiasis e.g. candidaemia, disseminated candidiasis. Cryptococcosis including cryptococcal meningitis and infections of other sites (e.g. pulmonary, cutaneous). For the prevention of fungal infections in patients with compromised immune function, patients with AIDS, organ transplant or other causes of immunosuppression.

Dosage and administration

The daily dose of **Canazole** should be based on the nature and severity of the fungal infections.

Adult:

- Vaginal candidiasis: A single dose of 150 mg.
- Tinea pedis, tinea corporis, tinea cruris: Recommended dose is 150 mg/week for 4-6 weeks, for tinea versicolor 400 mg single dose for 5 days.
- Onychomycosis: 150 mg per week for 12 months.
- Cryptococcal meningitis: 400mg on the first day followed by 200 mg or 400 mg once daily based on medical judgment of the patient's response to therapy up to 10-12 weeks after cerebrospinal fluid becomes culture negative.
- Oropharyngeal candidiasis: 200 mg on the first day followed by 100 mg once daily should be continued for at least 14 days.
- Esophageal candidiasis: 200 mg on the first day followed by 100 mg-400 mg once daily based on medical judgment of the patient's response to therapy. Treatment should continue for a minimum of three weeks and for at least two weeks following resolution of symptoms.

- Systemic candidiasis: The daily doses up to 400 mg based on medical judgment of the patient's response to therapy.
- Prophylaxis in patients undergoing bone marrow transplantation: 400 mg once daily.

Children:

Mucosal candidiasis

Children 12-18 years: 50 mg daily for 7-14 days for oropharyngeal candidiasis and 14-30 days for other mucosal infections.

Children 1 month-12 years: 3-6mg/kg on first day then 3 mg/kg daily for 7-14 days for oropharyngeal candidiasis and 14-30 days for other mucosal infections. Neonate 2-4 weeks: 3-6mg/kg on first day then 3 mg/kg every 48 hours. Neonate under 2 weeks: 3-6mg/kg on first day then 3 mg/kg every 72 hours.

Vaginal candidiasis

Children 16 -18 years: A single dose of 150 mg. Children under 16 years: A single dose of 150 mg.

Candidal balanitis

Children 16 -18 years: A single dose of 150 mg.

Tinea pedis, corporis, cruris, pityriasis versicolor, and dermal candidiasis

Children 1 month-18 years: 3mg/kg daily for 2-4 weeks (for up to 6 weeks in tinea pedis); maximum duration of treatment 6 weeks.

Invasive candidal infections (including candidaemia and disseminated candidiasis) and cryptococcal infections (including meningitis)

Child 1 month-18 years: 6-12 mg/kg (maximum 800 mg) daily, treatment continued according to response (at least 8 weeks for cryptococcal meningitis).

Neonate 2-4 weeks: 6-12 mg/kg every 48 hours, treatment continued according to response (at least 8 weeks for cryptococcal meningitis).

Neonate under 2 weeks: 6-12 mg/kg every 72 hours, treatment continued according to response (at least 8 weeks for cryptococcal meningitis).

Prevention of fungal infections in immunocompromised patients

Child 1 month-18 years: According to extent and duration of neutropenia, 3-12 mg/kg (maximum 400 mg) daily; 12 mg/kg (maximum 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.

Neonate 2-4 weeks: According to extent and duration of neutropenia, 3-12 mg/kg every 48 hours.

Neonate under 2 weeks: According to extent and duration of neutropenia, 3-12 mg/kg every 72 hours.

Use is pregnancy & lactation
Fluconazole is pregnancy Category C. Fluconazole should be used in pregnancy only if the potential benefit justifies the possible risk to the fetus. Use of Fluconazole in nursing mothers is not recommended.

Side effects
Fluconazole is generally well tolerated. The most common side effects associated with Fluconazole are symptoms associated with the gastro intestinal tract e.g. nausea, abdominal discomfort, diarrhea, headache, vomiting and flatulence. Other adverse effects such as rash are rarely encountered (incidence less than 1%).

Contraindications
Fluconazole is contraindicated in patients who have known hypersensitivity to Fluconazole or to any of its excipients. There is no information regarding cross-hypersensitivity between Fluconazole and other azole antifungal agents.

Precautions
Some azoles, including Fluconazole, have been associated with prolongation of the QT interval on the electrocardiogram. There have been rare cases of QT prolongation and torsade de pointes in patients taking Fluconazole. Most of these reports involved seriously ill patients with multiple confounding risk factors, such as structural heart disease, electrolyte abnormalities and concomitant medications that may have been contributory.

Drug interaction
Fluconazole concentration in plasma reduces by rifampicin but the effect of nicoumalone, phenytoin and warfarin is enhanced. Plasma concentration of sulphonylureas and theophyline is possibly increased.

Overdose
In the event of overdose, symptomatic treatment (with supportive measures and gastric lavage if clinically indicated) should be instituted. Fluconazole is largely excreted in urine. A three-hour hemodialysis session decreases plasma levels by approximately 50%.

Pharmaceutical precautions
Store in a cool and dry place & protected from light.

Presentation

Canazole Tablets 50 mg: Each tablet contains Fluconazole USP 50 mg.

Canazole Tablets 150 mg: Each tablet contains Fluconazole USP 150 mg.

Canazole Tablets 200 mg: Each tablet contains Fluconazole USP 200 mg.

Canazole Powder for Suspension: When reconstituted each 5m1 suspension contains Fluconazole USP 50 mg.

Package quantities
Canazole 50 mg tablet: Carton of 30 tablets in blister strips.

Canazole 150 mg tablet: Carton of 10 tablets in blister strips.

Canazole 200 mg tablet: Carton of 10 tablets in blister strips.

Canazole Powder for suspension: Bottle of Dry Powder for reconstitution in 35 ml of suspension.

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