Nispore®

Fluconazole 50 mg, 150 mg, 200 mg capsule
& Powder for Suspension

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Presentation

Nispore® 50: Each capsule contains Fluconazole USP 50 mg.
Nispore® 150: Each capsule contains Fluconazole USP 150 mg.
Nispore® 200: Each capsule contains Fluconazole USP 200 mg.
Nispore® Powder for Suspension: After reconstitution according to direction each 5 ml of suspension contains Fluconazole USP 50 mg.

Description

Fluconazole is a synthetic triazole antifungal drug that inhibits the biosynthesis of ergosterol, a major component of the cell membrane of yeast and fungal cells, leading to abnormalities in membrane permeabilities, inhibition of growth, abnormal cell wall formation and accumulation of intracellular lipids and membranous vesicles. It is active against a broad spectrum of yeast and other fungal pathogens. Following oral administration, absorption is rapid with > 90% of the dose being absorbed. Bioavailability is same whether taken during fasting or with food, as the pharmacokinetics of Fluconazole is relatively insensitive to physiological changes in the GIT. Unlike other azole drugs, the bioavailability of Fluconazole is unaffected by gastric pH so it can be given during treatment with antiulcer drugs including PPIs. 80% of a dose of Fluconazole is excreted unchanged and 11% is excreted as inactive metabolites in the urine, presumably as a result of metabolism in the liver. A further 2% of a dose is recovered unchanged in the feces, and the fate of the remaining is unknown.

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Dosage Guidelines

Indications	Dose	Duration
Vaginal Candidiasis	150 mg as a single oral dose	Once as a single oral dose
Oropharyngeal candidiasis	*Adult:* 200 mg on the 1st day, followed by 100 mg once daily *Child:* 6 mg/kg on the 1st day, followed by 3 mg/kg once daily	Up to 2 weeks following resolution of symptoms
Esophageal candidiasis	*Adult:* 200 mg on the 1st day, followed by 100 mg once daily Dosage up to 400 mg/day may be used based on patient's medical condition *Child:* 6 mg/kg on the 1st day, followed by 3 mg/kg once daily. Dosage up to 12 mg/kg/day may be used based on patient's medical condition	Up to 2-3 weeks following resolution of symptoms
Systemic candida infections	*Adult:* Daily doses of 400 mg may be used *Child:* Daily doses of 6-12 mg/kg/day may be used	
Cryptococcal meningitis	*Adult:* 400 mg on the 1st day, followed by 200 mg once daily. Dosage up to 400 mg/day may be used based on patient's medical condition. For suppression of relapse of cryptococcal meningitis in patients with AIDS, the recommended dose is 200 mg once daily *Child:* 12 mg/kg on the 1st day, followed by 6 mg/kg once daily. Dosage up to 12 mg/kg/day may be used based on patient's medical condition. For suppression of relapse of Cryptococcal meningitis with AIDS, the recommended dose is 6 mg/kg once daily	Up to 10-12 weeks after the cerebrospinal fluid becomes culture negative
Patients undergone bone marrow transplantation	400 mg once daily	Up to 7 days after the neutrophil count rises above 1000 cells per cu mm
UTI with candida and peritonitis	Daily doses of 50-200 mg may be used	

Patients with impaired renal function:

No need to adjust single dose therapy of Fluconazole for vaginal candidiasis. In case of multiple dose, an initial loading dose of 50 to 400 mg should be given. After the loading dose, the daily dose (according to indication) should be based on the following:

Creatinine Clearance (ml/min)	% of recommended dosage
>50	100%
< 50 (no dialysis)	50%
Regular dialysis	100% after each dialysis

Side effects

Nausea, abdominal discomfort, diarrhoea, flatulence, headache, rash; less frequently dyspepsia, vomiting, abnormalities in liver enzymes, seizures, alopecia and Stevens Johnson syndrome reported.

Precautions

Cautions should be taken in renal impairment; in hepatic disease liver function should be monitored and should be discontinued if signs or symptoms of hepatic disease appear.

Use in pregnancy and 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.

Contraindications

- Known hypersensitivity
- Advanced liver disease

Drug interactions

Fluconazole decreases the metabolism of Cyclosporine and Phenytoin and increases the AUC of Retinoic acid. Fluconazole increases bleeding time in patients treated with Warfarin. Concomitant use of Fluconazole decreases in the mean plasma clearance of Theophyllin and increases the plasma levels of Zidovudine and concentration of Oral hypoglycemics. Rifampin induces the metabolism of Fluconazole.

Over dosage

In the case of an overdose, supportive measures should be instituted.

Directions for reconstitution of suspension

Shake the bottle well to loosen the powder. Add 20 ml (4 measuring spoonful) of boiled and cooled water to the dry mixture in the bottle. For ease of preparation add water to the bottle in two portions. Shake the bottle well after each addition of water until all the powder is in suspension.

Note: Shake the suspension well before each use. Keep the bottle tightly closed. The reconstituted suspension should be stored in a cool and dry place, preferably in refrigerator and unused portion should be discarded after 14 days.

Storage

Do not store above 30° C. Keep away from light and out of the reach of children.

Commercial pack

Nispore® 50: Each box contains 3 blister strips of 10 capsules.
Nispore® 150: Each box contains 2 blister strips of 10 capsules.
Nispore® 200: Each box contains 1 blister strip of 10 capsules.
Nispore® Powder for Suspension: Each bottle contains dry powder to produce 35 ml suspension when reconstituted.

Manufactured by
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