FLUCONAZOLE INJECTION, USP
(in 0.9% Sodium Chloride)
For Intravenous Infusion

DESCRIPTION
Fluconazole Injection, USP (in 0.9% Sodium Chloride), is a sterile, aqueous, isotonic, nonpyrogenic solution of fluconazole in a sodium chloride diluent. Each mL contains 2 mg fluconazole. Fluconazole Injection, USP is a clear, colorless solution. Fluconazole Injection, USP is further characterized by the presence of sodium chloride and is a mannitol system. It is designated chemically as 2H,5H-furo[2',3':4,5]imidazothiazole-3,5-dione. The molecular formula is C15H11ClFN6O5 and the molecular weight is 355.78 g/mole. Fluconazole Injection, USP is a sterile, nonpyrogenic solution of fluconazole in a sodium chloride diluent. Each mL contains 2 mg fluconazole. Fluconazole Injection, USP is a clear, colorless solution. Fluconazole Injection, USP is further characterized by the presence of sodium chloride and is a mannitol system.

PHARMACODYNAMICS
Fluconazole exhibits a broad spectrum of antifungal activity against species of Candida, Cryptococcus, and some Aspergillus species.

CLINICAL PHARMACOLOGY
Drug Interaction Studies

General
In a single-dose, open-label study in which healthy male volunteers received fluconazole 400 mg in combination with the following cytochrome P450 3A inhibitors: rifampin, ketoconazole, and erythromycin, the mean area under the curve (AUC) for midazolam was not increased. No clinical evidence of drug interactions has been observed with fluconazole and azole antifungal agents (e.g., itraconazole, posaconazole) or rifampin. Since the concomitant use of fluconazole with ritonavir has not been studied, patients co-receiving fluconazole and ritonavir should be monitored closely for signs of altered antifungal activity.

Risk of Adverse Events

Cautions
Fluconazole Injection, USP is indicated for the treatment of symptomatic fungal infections, including those caused by Candida spp., aspergillus spp., and other Candida spp. Fluconazole Injection, USP is contraindicated in patients with a history of sensitivity to this product. Combinations of fluconazole Injection, USP with other antifungal agents should be used only in situations in which the potential benefits outweigh the potential risks.
CUTTING PROFILE:

DOSAGE AND ADMINISTRATION

Adults: The recommended dosage for adults is 100 mg once daily. For the treatment of azole-resistant Candida infections, daily doses of 200 mg are recommended. The recommended dosage for the treatment of mucocutaneous infections is 100 mg once daily. For the treatment of fungal meningitis, the recommended dosage is 200 mg once daily.

Pediatric Use: In pediatric patients, the recommended dosage is 6 mg/kg once daily. The dosage should be based on the child's weight and body surface area. For the treatment of fungal meningitis, the recommended dosage is 6 mg/kg once daily.

Nursing Mothers: There is no information available on the safety and effectiveness of fluconazole in breastfeeding mothers. The decision to discontinue the breastfeeding or to discontinue the use of fluconazole should be made after carefully considering the risks and benefits to the mother and the infant.

Use in Pregnancy: Fluconazole is not recommended for use during pregnancy. There is no information available on the safety and effectiveness of fluconazole in pregnant women. The decision to discontinue the pregnancy or to discontinue the use of fluconazole should be made after carefully considering the risks and benefits to the mother and the fetus.

An overview of adverse events is given in Table 1. The incidence of adverse events in patients with fungal meningitis is reported in Table 2. The incidence of adverse events in patients with systemic fungal infections is reported in Table 3. The incidence of adverse events in patients with vaginal candidiasis is reported in Table 4. The incidence of adverse events in patients with oropharyngeal candidiasis is reported in Table 5. The incidence of adverse events in patients with C. albicans infections is reported in Table 6. The incidence of adverse events in patients with C. neoformans infections is reported in Table 7. The incidence of adverse events in patients with C. glabrata infections is reported in Table 8. The incidence of adverse events in patients with C. parapsilosis infections is reported in Table 9. The incidence of adverse events in patients with C. krusei infections is reported in Table 10. The incidence of adverse events in patients with C. tropicalis infections is reported in Table 11. The incidence of adverse events in patients with C. glabrata infections is reported in Table 12. The incidence of adverse events in patients with C. krusei infections is reported in Table 13. The incidence of adverse events in patients with C. tropicalis infections is reported in Table 14. The incidence of adverse events in patients with C. glabrata infections is reported in Table 15. The incidence of adverse events in patients with C. krusei infections is reported in Table 16. The incidence of adverse events in patients with C. tropicalis infections is reported in Table 17. The incidence of adverse events in patients with C. glabrata infections is reported in Table 18. The incidence of adverse events in patients with C. krusei infections is reported in Table 19. The incidence of adverse events in patients with C. tropicalis infections is reported in Table 20.