

Fluconazole (Diflucan®)

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Fluconazole (Diflucan®, Roerig, New York, NY) was recently developed for the treatment of systemic and surface fungal infections. It is an azole in the same family as ketoconazole and itraconazole. Fluconazole has several advantages over the other antifungal drugs including the option of oral therapy. The side-effect profile is minimal. Studies have shown it to be efficacious for the treatment of vaginal yeast infections in a single oral dose.

STRUCTURE AND DERIVATION

Fluconazole [(difluoro-2,4-phenyl)-2-bis(1H-triazole-1,2)-4-yl-1)-1,3-propanol-2] is an azole antifungal agent. The imidazole, i.e., ketoconazole, has been modified by the replacement of the imidazole ring with a triazole ring, addition of a second triazole ring, and substitution of a difluorophenyl moiety for a dichlorophenyl moiety. These changes provide more selective inhibition of fungal enzyme systems, greater metabolic stability, and enhanced water solubility.¹

MECHANISM OF ACTION

Fluconazole interferes with the cytochrome P-450-dependent enzyme C-14 α -demethylase, which is responsible for production of ergosterol, the major component of the fungal cell membrane. The disruption of ergosterol synthesis causes structural and functional changes in the membrane which predispose the fungus to osmotic and immune-mediated damage and interfere with cell adherence.² The triazole derivatives bind to the cytochrome P-450 enzyme with greater specificity than their predecessors. Additional antifungal activity may be accounted for by the azole inhibition of cytochrome *c* oxidative and peroxidative enzymes, leading to increased intracellular peroxidase.³⁻⁵

PHARMACOKINETICS

Fluconazole is water-soluble and thus is readily absorbed from the gastrointestinal tract. The peak plasma concentration in humans, which is reached 2 h after dosing, is 2.44–3.58 $\mu\text{g/ml}$ after a 150-mg dose.⁶ The presence of food does not affect the absorption of fluconazole but delays the time to maximum serum concentration until 4 h after dosing.⁷ The bioavailability of fluconazole is not affected by gastric pH.^{8,9} The amount of fluconazole absorbed is linearly proportional to the dose, and urinary excretion data indicate that the oral bioavailability of fluconazole is 80–90%.

Fluconazole has a volume of distribution that closely approximates total body water, 0.6–0.8 l/kg.⁶ Roughly 10% of fluconazole is protein-bound in humans.⁶ This low degree of binding facilitates the transfer of the drug into the central nervous system regardless of the presence of inflammation of the meninges.¹⁰⁻¹² Penetration of the drug into the skin and nails has been demonstrated in humans.¹³ Houang et al.⁴ found fluconazole to be persistent in vaginal secretions with concentrations above the MIC for *Candida albicans* for at least 72 h after a single 150-mg oral dose.

Very little metabolism of fluconazole occurs; the vast majority of it is eliminated intact through the kidney. Humphrey et al.⁶ detected 3 metabolites of fluconazole in the urine of treated dogs and mice, but they comprised only 4% of the total administered drug. Two primary mechanisms influence the elimination. First, the drug is rapidly filtered as a result of the small amount of protein binding. Fluconazole is then extensively reabsorbed by the tubules, explaining its long half-life.¹⁴

Caution must be exercised in the administration of fluconazole to patients with impaired renal func-

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