

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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Table of Contents Fluconazole A Medical Dictionary Bibliography A

1. Understanding the eBook Fluconazole A Medical Dictionary Bibliography A
 - The Rise of Digital Reading Fluconazole A Medical Dictionary Bibliography A
 - Advantages of eBooks Over Traditional Books
2. Identifying Fluconazole A Medical Dictionary Bibliography A
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Fluconazole A Medical Dictionary Bibliography A
 - User-Friendly Interface
4. Exploring eBook Recommendations from Fluconazole A Medical Dictionary Bibliography A

- Personalized Recommendations
- Fluconazole A Medical Dictionary Bibliography A User Reviews and Ratings
- Fluconazole A Medical Dictionary Bibliography A and Bestseller Lists
- 5. Accessing Fluconazole A Medical Dictionary Bibliography A Free and Paid eBooks
 - Fluconazole A Medical Dictionary Bibliography A Public Domain eBooks
 - Fluconazole A Medical Dictionary Bibliography A eBook Subscription Services
 - Fluconazole A Medical Dictionary Bibliography A Budget-Friendly Options
- 6. Navigating Fluconazole A Medical Dictionary Bibliography A eBook Formats
 - ePub, PDF, MOBI, and More
 - Fluconazole A Medical Dictionary Bibliography A Compatibility with Devices
 - Fluconazole A Medical Dictionary Bibliography A Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Fluconazole A Medical Dictionary Bibliography A
 - Highlighting and Note-Taking Fluconazole A Medical Dictionary Bibliography A
 - Interactive Elements Fluconazole A Medical Dictionary Bibliography A
- 8. Staying Engaged with Fluconazole A Medical Dictionary Bibliography A
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Fluconazole A Medical Dictionary Bibliography A
- 9. Balancing eBooks and Physical Books Fluconazole A Medical Dictionary Bibliography A
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Fluconazole A Medical Dictionary Bibliography A
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Fluconazole A Medical Dictionary Bibliography A
 - Setting Reading Goals Fluconazole A Medical Dictionary Bibliography A
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Fluconazole A Medical Dictionary Bibliography A

- Fact-Checking eBook Content of Fluconazole A Medical Dictionary Bibliography A
- Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
- 14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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