

The second generation Fungicide



Produced by *CIPLA*, a leading provider of generic pharmaceuticals.

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Key Facts about CIPLA:

- 25 manufacturing facilities approved by leading regulatory authorities including the FDA (USA), MHRA (U.K.) and TGA (Australia).
- Over 1000 Formulations and 150 actives Active Pharmaceutical Ingredients.
- Pregualified and Approved by the World Health Organisation (WHO) for supply to UN Agencies.
- The World's largest range of antiasthmatic aerosols and inhalation devices.
- The World's largest manufacturer of antiretroviral drugs and supplier to the Clinton Foundation AIDS/HIV Initiative.

Terbifin - The Second Generation Fungicide

Superior Therapy in Superficial Fungal and Nail Infections:

"Oral terbinafine has shown efficacy in treatment of tinea pedis, tinea cruris, tinea corporis and onychomycoses" Postgraduate Medicine Jan 2001; 109(1): 117-32

Superior to Itraconazole

More Effective:

"In the treatment of onychomycosis, continuous terbinafine provided superior long-term mycological and clinical efficacy and lower rates of mycological and clinical relapse compared with intermittent itraconazole."

Arch Dermatol 2002; 138:353-57

"From four trials comparing terbinafine to itraconazole, a statistically significant advantage in favour of terbinafine was observed for negative culture and microscopy at the end of the trials. Furthermore, both patients and physicians reported terbinafine to be better tolerated than itraconazole."

Br J Derm 2002 July; 147(1): 118

Less Expensive:

"Continuous terbinafine is less costly and more effective than intermittent itraconazole in the treatment of dermatophyte toenail onychomycosis."

Pharmacoeconomics 2001; 19(40): 401-10

More effective than Fluconazole

Terbinafine 250 mg daily for 12 weeks is significantly more effective in the treatment of onychomycosis than fluconazole 150 mg once weekly for either 12 or 24 weeks."

Br J Dermatol. 2000 Jan; 142(1): 97-102

"Fluconazole, at these doses and treatment durations, was the least effective. With regard to cost-effectiveness, side effects and the cure rates, terbinafine could be the drug of choice in the short-term treatment of toenail onychomycosis."

J Dermatolog Treat. 2002 Mar; 13(1): 3-9

Better tolerated than Ketoconazole

"Ketoconazole's cure rate is similar, but its use in cutaneous infections is limited by multiple drug interactions and serious side effects." The Journal of Family Practice 2002 Jan Vol. 51, No. 1



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Terbinafine may be the most rational choice of oral antifungal agent in patients receiving concomitant medications that may adversely affect or be affected by either Fluconazole or Itraconazole.

H. I. Katz Drug Interactions of the newer oral antifungal agents, British Journal of Dermatology 1999: 141 (Suppl. 56) 26-3

Potential or theoretical consequences of drug interactions							
Interacting drug		Fluconazole	Itraconazole	Terbinafine			
Anti-diabetic drugs	Glipizide	1	1				
	Glibenclamide (Glyburide)	1	1				
	Tolbutamide	✓	1				
Anti-ulcer drugs	Antacids		1				
	Ranitidine		1				
	Cimetidine	✓	1	1			
	Sucralfate		1				
Anti-epileptic drugs	Carbamazepine		1				
	Phenytoin	1	1				
Anti-viral drugs	Didaosine		1				
•	Ritonavir	1	1				
	Zidovudine	1					
Anti-coagulants	Warfarin	1	1				
Anxiolytics,	Midazolam	✓	1				
Sedatives	Triazolam	✓	1				
Hypnotics	Alprazolam	1	1				
	Diazepam	✓	1				
Anti-hypertensives	Felodipine	✓	✓				
3	Nifedipine		1				
Glucocorticoids	Methyl prednisolone	1	1				
Bronchodilator	Theophylline	1					
Anti TB drugs	Rifampicin	1	1	1			
Ů	Rifabutin	1	1				
	Isoniazide		✓				
Lipid Lowering Agents	Lovastatin	1	1				
	Simvastatin	1	1				
Diuretics	Hydrochlorothiazide	1					
Impotence drugs	Sildenafil	1	✓				
Immunosuppressants	Cyclosporin	1	1	1			
11	Tacrolimus	1	1				
Anti arrhythmics	Quinidine	1	1				
lonotrpoic agent	Digoxin	1	1				

Key finding: The low potential of interaction between terbinafine and the cytochrome P-450 enzyme system explains why clinically significant interactions between terbinafine and agents metabolized by these enzymes are few.

DOSAGE CHART

	INDICATIONS	DOSAGE	TREATMENT TIME
Tablets (Adults)	Onychomycosis (Fingernail)	One tablet 250 mg daily	6 Weeks
	Onychomycosis (Toenail)	One tablet 250 mg daily	12 Weeks
	Tinea Pedis / Manuum	One tablet 250 mg daily	2-6 Weeks
	Tinea Corporis / Cruris	One tablet 250 mg daily	2-4 Weeks
	Tinea Capitis	One tablet 250 mg daily	4 Weeks

Tablets	INDICATIONS	WEIGHT	DOSAGE	TREATMENT TIME
(Children		Children < 20 kg	62.5 mg (1/4 tablet)	Once daily for 4 weeks
over 2 years) Tinea Capiti	Tinea Canitis	Children 20 kg - 40 kg	125 mg (1/2 tablet)	Once daily for 4 weeks
	Tillea Gapitis	Children > 40 kg	250 mg (1 tablet)	Once daily for 4 weeks



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