

A critical appraisal of once-daily topical luliconazole for the treatment of superficial fungal infections

- Superficial fungal infections (tinea pedis, cruris, corporis) affect 20–25% of the global population.
- Standard topical antifungals include allylamines (terbinafine, butenafine) & imidazoles (clotrimazole, bifonazole).
- Limitations: resistance, long treatment courses, and poor patient compliance.



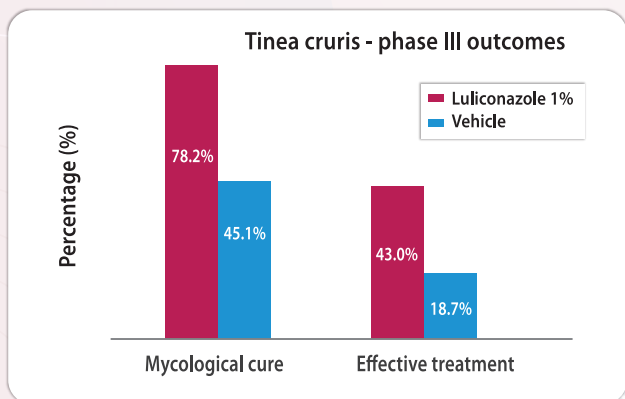
Study design	Phase II/III RCTs & comparative trials			
Patients  ~1,800	Duration  1 - 2 weeks (vs 2–4 weeks comparators)	Comparators Vehicle, terbinafine, clotrimazole, bifonazole, sertaconazole	Intervention Luliconazole 1% cream once daily	Key Outcomes High clinical & mycological cure up to ~88%; efficacy comparable or superior; shorter course; well tolerated

Table: MICs (µg/ml) of antifungals vs common pathogens

Pathogen	Luliconazole	Terbinafine	Clotrimazole
T. rubrum	0.00012–0.004	0.002–0.25	0.031–0.063
T. mentagrophytes	0.00024–0.002	0.001–0.06	0.016–0.5
T. tonsurans	0.00024–0.00049	0.0098–0.016	0.13–1



Conclusion

Luliconazole 1% cream is:

- Highly effective against superficial dermatophytoses.
- Provides effective outcomes within a shorter treatment course of one to two weeks, compared to traditional antifungals.
- Well tolerated with mild, localized adverse effects.

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Luliconazole: A Novel Imidazole for Superficial Fungal Infections



Intelligence applied. Benefits multiplied

Drug Review

An overview of dermatophytosis

- Fungal infections (superficial and invasive) are a major health problem and an important cause of morbidity. Superficial fungal infections affect as many as 20%–25% of the world's population and are associated with interference with daily activities, poor quality of life, and health care expenditure.
- Dermatophytosis usually remain localized to the superficial layers of the skin, hair, or nails. They are also commonly known as ringworms for its characteristic ring-shaped lesions.

Challenges in the treatment of fungal infections

- Adequate treatment of cutaneous mycoses with current antifungals often requires long courses, but patients discontinue early once symptoms subside, leaving fungi behind and causing relapses. Short-course, fungicidal agents that ensure mycological clearance are therefore highly needed.
- The ideal topical antifungal should provide broad-spectrum fungicidal activity at low doses, convenient once-daily use, keratinophilic/lipophilic action, high cure rates with reservoir effect, minimal resistance or relapse, good safety, and affordability.

Luliconazole: redefining standards in topical antifungal therapy

Luliconazole is a novel, optimally micronized imidazole antifungal designed to address the persistent challenges in dermatophytosis management. Its clinical efficacy, rapid action, and patient-friendly regimen make it a superior choice in topical antifungal therapy. It has:

- **Robust antifungal activity:** Demonstrates strong fungicidal action against common dermatophytes, ensuring comprehensive pathogen clearance.
- **Simplified treatment regimen:** Once-daily dosing with short treatment duration (1 week for tinea cruris/corporis, 2 weeks for tinea pedis), improving adherence and compliance.
- **Enhanced skin penetration:** Micronized formulation (<25 microns) achieves deeper tissue penetration for effective eradication of residual fungi.
- **Proven clinical outcomes:** Randomized trials confirm high clinical and mycological cure rates with significantly lower relapse compared to vehicle.
- **Excellent safety profile:** Well-tolerated with minimal localized adverse events (<1%), ensuring high patient acceptability.

Table 1: Efficacy results at 4 weeks post-treatment- interdigital tinea pedis

	Study 1		Study 2	
	LULICONAZOLE Cream, 1% N= 106 n (%)	Vehicle Cream N= 103 n (%)	LULICONAZOLE Cream, 1% N= 107 n (%)	Vehicle Cream N= 107 n (%)
Complete Clearance	28 (26%)	2 (2%)	15 (14%)	3 (3%)
Effective Treatment	51 (48%)	10 (10%)	35 (33%)	16 (15%)
Clinical Cure	31 (29%)	8 (8%)	16 (15%)	4 (4%)
Mycological Cure	66 (62%)	18 (18%)	60 (56%)	29 (27%)

Table 2: Efficacy results at 3 weeks post treatment- tinea cruris

	LULICONAZOLE Cream, 1% N= 165 n (%)	Vehicle Cream N= 91 n (%)
Complete Clearance	35 (21%)	4 (4%)
Effective Treatment	71 (43%)	17 (19%)
Clinical Cure	40 (24%)	6 (7%)
Mycological Cure	129 (78%)	41 (45%)

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