

Optazan[®] | TOPICAL CREAM (sertaconazole 2%)

Broad spectrum antifungal with anti-inflammatory and antibacterial properties

Sertaconazole is an azole antifungal indicated for the topical treatment of interdigital tinea pedis in immunocompetent adult and pediatric patients 12 years of age and older caused by *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*.¹



An Evolutionary Azole with a Dual-Action Mechanism¹⁻⁴



Inhibits ergosterol synthesis (azole effect)



Directly damages fungal membrane



Fungistatic (via ergosterol inhabitation) + Fungicidal (via membrane disruption)

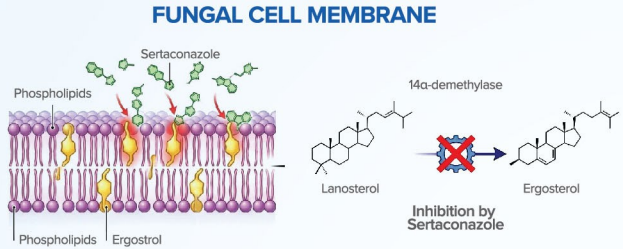
Mechanism of Action

Dual-Action Antifungal Activity¹⁻⁴

1

INHIBITION OF ERGOSTEROL SYNTHESIS

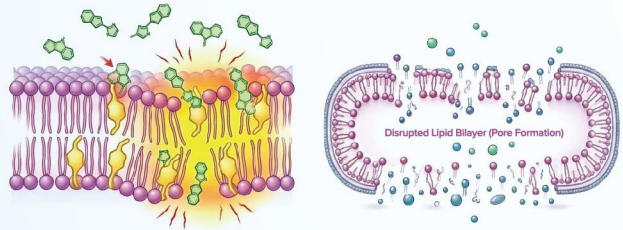
- Sertaconazole inhibits 14 α -demethylase (CYP51 enzyme)
- ↓ Ergosterol production
- → Membrane instability



2

DIRECT MEMBRANE DAMAGE

- Binds non-sterol lipids
- Creates pores in membrane
- → Leakage of intracellular contents



FINAL EFFECTS



FUNGISTATIC (VIA ERGOSTEROL INHIBITION)

Inhibits fungal growth by disrupting ergosterol synthesis and membrane stability.



DIRECT MEMBRANE DAMAGE (VIA MEMBRANE DISRUPTION)

Causes structural damage to the cell membrane leading to leakage of intracellular contents and fungal cell death.

Optazan® Sertaconazole is a next-generation topical antifungal that combines potent antifungal activity with anti-inflammatory benefits, offering both mycological cure and rapid symptom relief.

Key Benefits



Broad-spectrum Antifungal⁵

Effective against dermatophytes, yeasts & molds



Dual Mechanism of action⁶

Targets fungi in two ways for superior efficacy and lower resistance risk



Rapid Symptom Relief^{7,8}

Early reduction in: Pruritus, Erythema and Scaling



Anti-inflammatory Benefit⁹

- Reduces inflammatory signs
- Useful in symptomatic tinea pedis



Excellent Safety Profile¹⁰

- Minimal systemic absorption
- Very low irritation

Who are the eligible patients for treatment with Optazan® Sertaconazole?



Inflammatory tinea pedis



Patients with severe itching



Sensitive skin patients



Recurrent infections

Proven Clinical Safety

Strong Safety Profile:

Optazan® Sertaconazole is generally well tolerated, with adverse effects mostly limited to **mild, transient** local adverse effects such as contact dermatitis, burning, erythema, or itching.¹⁻¹¹

Minimal Systemic Absorption:

Studies consistently show undetectable plasma concentrations following topical administration, significantly **reducing the risk of systemic toxicity and drug interactions**, including warfarin and other sensitive medications.³

Administration¹

Apply Optazan® cream 2% to the affected and immediate surrounding area(s) twice daily for 4 weeks.

Product Information¹²:

INDICATIONS AND USAGE: OPTAZAN cream 2% is an azole antifungal indicated for the topical treatment of interdigital tinea pedis in immunocompetent patients 12 years of age and older, caused by: *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*. **DOSAGE AND ADMINISTRATION:** Apply OPTAZAN cream, 2% twice daily for 4 weeks. Apply a sufficient amount of OPTAZAN cream, 2% to cover both the affected areas between the toes and the immediately surrounding healthy skin. • Use OPTAZAN cream, 2% for the full treatment time recommended by the physician, even though symptoms may have improved. • Dry the affected area(s) thoroughly before application, if using OPTAZAN cream, 2% after bathing. • Wash hands after use. • Avoid the use of occlusive dressings or wrappings. • For topical use. • Not for ophthalmic, oral, or intravaginal use. **DOSAGE FORMS AND STRENGTHS:** Cream 2%. Each gram of OPTAZAN cream, 2%, contains 17.5 mg of sertaconazole (as sertaconazole nitrate, 20 mg) in a white cream base. **CONTRAINDICATIONS:** None. **LOCAL ADVERSE REACTIONS:** Most common adverse reactions observed in clinical trials (incidence >2%) were contact dermatitis, dry skin, burning skin, application site skin tenderness.

References:

1. ERTACZO (Sertaconazole) [package insert]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021385s006lbl.pdf.
2. Carrillo-Muñoz AJ, Tur-Tur C, Hernández-Molina JM, et al. Sertaconazole: an updated review of its antifungal activity, mechanism of action and clinical efficacy. *Expert Rev Anti Infect Ther*. 2013;11(4):347–358.
3. Croxall JD, Plosker GL. Sertaconazole: a review of its use in superficial mycoses. *Drugs*. 2009;69(3):339–359.
4. Agut J, Pelácin C, Sacristán A, et al. Inhibition of ergosterol synthesis by sertaconazole in *Candida albicans*. *Arzneimittelforschung*. 1992;42(5A):718–720.
5. Carrillo-Muñoz AJ, Tur-Tur C, Cárdenas DC, et al. Sertaconazole nitrate shows fungicidal and fungistatic activities against *Trichophyton rubrum*, *Trichophyton mentagrophytes*, and *Epidermophyton floccosum*, causative agents of tinea pedis. *Antimicrob Agents Chemother*. 2011 Sep;55(9):4420-1.
6. Carrillo-Muñoz AJ, Tur-Tur C, Giusiano G, et al. Sertaconazole: an antifungal agent for the topical treatment of superficial candidiasis. *Expert Rev Anti Infect Ther*. 2013 Apr;11(4):347-58.
7. Kirckil LH. Observational evaluation of sertaconazole nitrate cream 2% in the treatment of pruritus related to tinea pedis. *Cutis*. 2009 Nov;84(5):279-83.
8. Sharma A, Saple DG, Surjushe A, et al. Efficacy and tolerability of sertaconazole nitrate 2% cream vs. miconazole in patients with cutaneous dermatophytosis. *Mycoses*. 2011;54(3):217-22.
9. Liebel F, Lyte P, Garay M, et al. Anti-inflammatory and anti-itch activity of sertaconazole nitrate. *Arch Dermatol Res*. 2006;298(4):191-9.
10. Khondker L. Efficacy and safety of sertaconazole in the treatment of dermatophytoses. *Journal of Pakistan Association of Dermatologists*. 2021 Mar 4;31(1):42-50.
11. Chatterjee D, Ghosh SK, Sen S, et al. Efficacy and tolerability of topical sertaconazole versus topical terbinafine in localized dermatophytosis: A randomized, observer-blind, parallel group study. *Indian J Pharmacol*. 2016;48(6):659-664.
12. Sertaconazole Nitrate cream, 2%, for topical use Initial. FDA Label 2020. Reference ID: 4718873



BEHVAZAN
Pharmaceutical Co.

Optazan[®]

TOPICAL CREAM
(sertaconazole 2%)

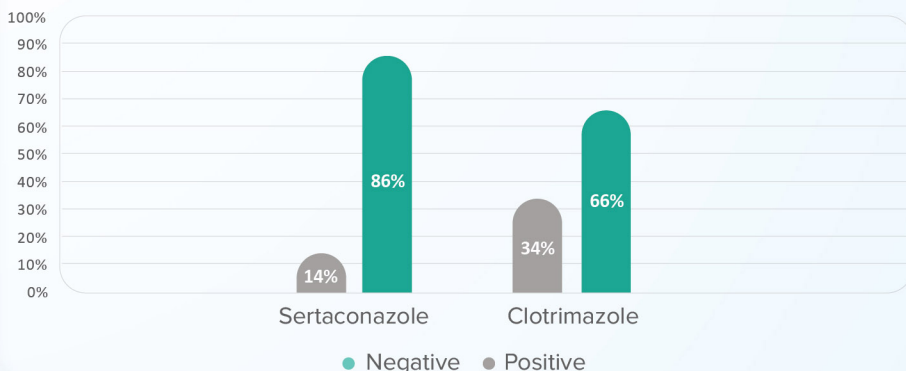
BEYOND FUNGICIDAL A Dual-Action Antifungal with Anti-Inflammatory Benefits.



Sertaconazole vs Clotrimazole

In tinea pedis treatment, Topical Optazan[®]Sertaconazole 2% cream demonstrated superior efficacy and safety compared with Clotrimazole 1% cream, with Topical greater improvement in clinical signs and symptoms.²

Comparison of efficacy* of Sertaconazole cream 2% vs Clotrimazole 1%

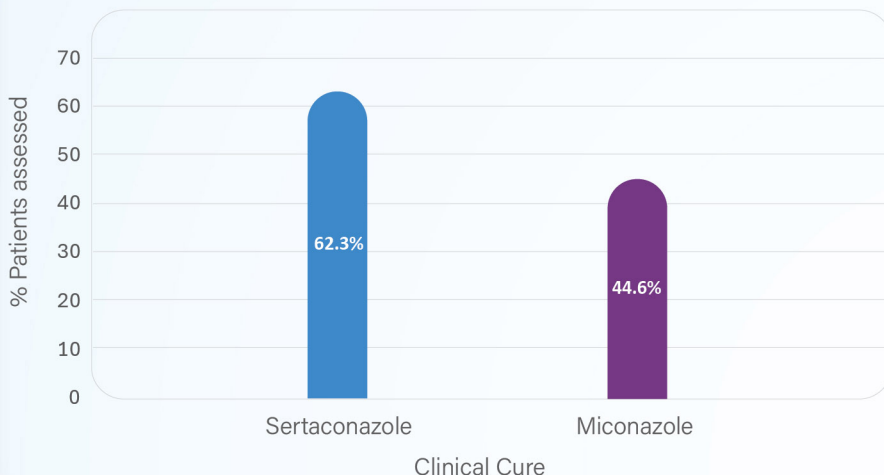


* Efficacy was also assessed on the basis of reduction of total composite score of more than 2 with negative KoH test.

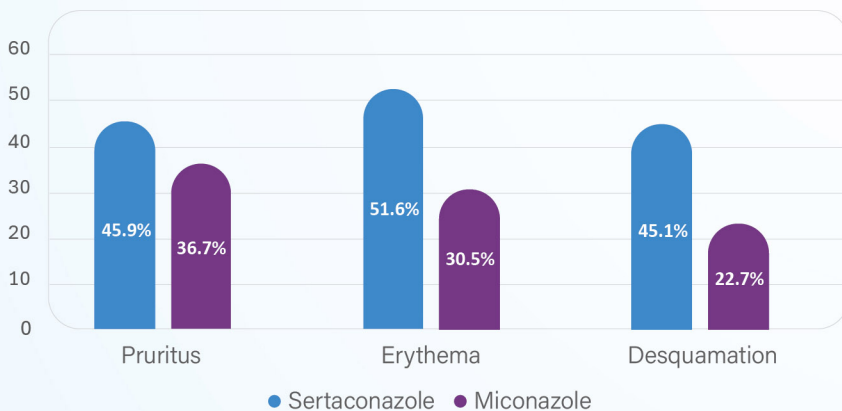
Sertaconazole vs Miconazole

Topical Optazan® Sertaconazole cream (2%) provides a better efficacy and tolerability compared with Topical Miconazole cream (2%).³

Overall Global Assessment



Comparison of Changes at the End of Week 2

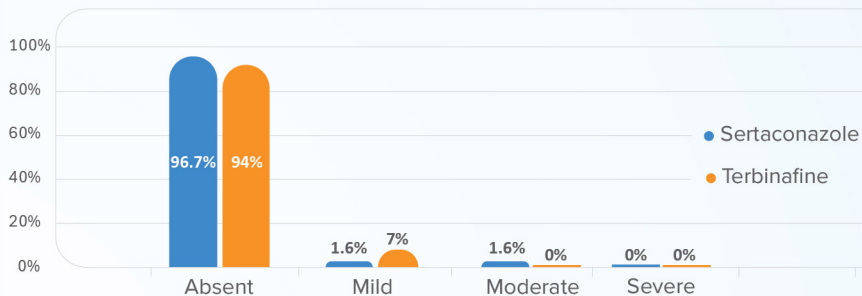


Topical Optazan® Sertaconazole 2% demonstrated higher fungicidal activity in in-vitro studies compared with tested imidazoles, outperforming Miconazole, Clotrimazole, and Ketoconazole.

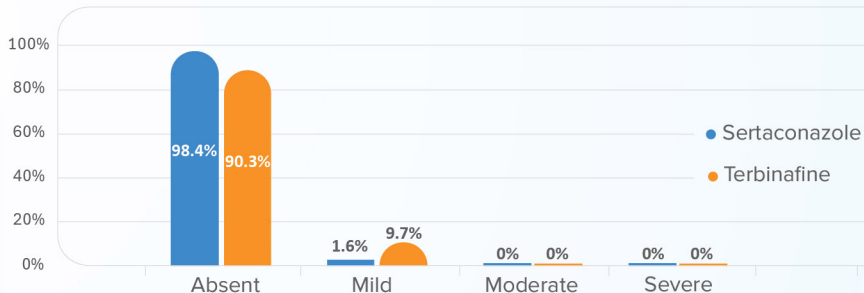
Sertaconazole vs Terbinafine

Topical Optazan® Sertaconazole 2% demonstrated faster mycological cure, better pruritus and erythema reduction, and an improved safety profile compared with topical Terbinafine 1%.¹

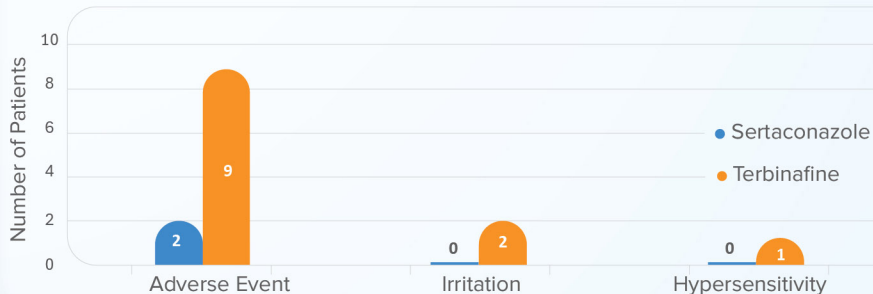
The percentage of patients showing symptoms of pruritus at the end of 4 weeks (follow up phase)



The percentage of patients showing improvement of erythema severity at the end of 4 weeks (follow up phase)



Incidence of adverse events during 4 weeks of study period



	Sertaconazole	Terbinafine	Miconazole	Clotrimazole
Mechanism	Ergosterol inhibition + direct membrane damage (fungicidal & fungistatic)	Squalene epoxidase inhibition (primarily fungicidal)	Ergosterol inhibition	Ergosterol inhibition
Antifungal Spectrum	Broad spectrum; active against dermatophytes, Candida, Gram-positive bacteria	Strong dermatophyte activity	Broad antifungal and anti-yeast activity	Broad antifungal activity
Clinical Efficacy	Superior or comparable efficacy in tinea pedis, corporis, and cruris; faster symptom resolution	Excellent dermatophyte clearance with shorter therapy duration	Effective in candidiasis and superficial mycoses	Effective and widely used standard therapy
Mycological Cure	Faster and higher cure rates reported in several comparative studies	High cure rate, especially in dermatophyte infections	Good cure rates	Good cure rates
Pruritus Relief	Strong antipruritic and anti-inflammatory effect	Moderate symptom relief	Moderate relief	Moderate relief
Common Adverse Effects	Mild erythema, dryness, transient burning, rare dermatitis	Burning, irritation, itching	Irritation, redness, contact dermatitis (rare)	Mild burning, irritation
Resistance Potential	Low reported resistance; active against some azole-resistant strains	Low resistance in dermatophytes	Some emerging resistance reports	Resistance observed in prolonged/recurrent infections
Additional Advantages	Anti-inflammatory, antipruritic, prolonged skin retention, fungicidal action among azoles	Shorter treatment duration and once-daily dosing	Widely available OTC; useful for Candida infections	Cost-effective and extensively studied
Dermal Retention	High lipophilicity enables prolonged retention in stratum corneum	Reservoir effect in epidermis	Moderate	Moderate

References:

- Borgohain M, Elango P, Chellathai D. Comparative study of the efficacy and safety of topical sertaconazole versus topical terbinafine in the treatment of dermatophytoses in a tertiary care centre. *Int J Basic Clin Pharmacol* 2016;5:855-61.
- Ghafoor R, Batool H, Shafi S, et al. Comparison of Efficacy of Sertaconazole Nitrate Cream 2 Percent vs Clotrimazole 1 Percent for the Treatment of Tinea Pedis. *Indus Journal of Bioscience Research*. 2025 11;3(7):316-21.
- Sharma A, Saple DG, Surjushe A, et al. Efficacy and tolerability of sertaconazole nitrate 2% cream vs. miconazole in patients with cutaneous dermatophytosis. *Mycoses*. 2011;54(3):217-22.
- Croxtall JD, Plosker GL. Sertaconazole: a review of its use in the management of superficial mycoses in dermatology and gynaecology. *Drugs*. 2009;69(3):339-59.
- Chatterjee D, Ghosh SK, Sen S, et al. Efficacy and tolerability of topical sertaconazole versus topical terbinafine in localized dermatophytosis: A randomized, observer-blind, parallel group study. *Indian J Pharmacol*. 2016;48(6):659-664.
- Carrillo-Muñoz AJ, Giusiano G, Ezkurra PA, et al. Sertaconazole: updated review of a topical antifungal agent. *Expert review of anti-infective therapy*. 2005 1;3(3):333-42.



BEHVAZAN
Pharmaceutical Co.

eRX Code:
73989