

CONVENIENT AUTO-REFILL PROGRAM



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Prescription Required

Manufacturer: TOLMAR INC.

NDC 63646001004

Ketoconazole 2% Shampoo (Generic Nizoral)

GENERIC

Out of Stock

Product Information



Uses **Dosage and Administration** **Cautions** **Pharmacokinetics**



Uses

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Dermatophytoses

Ketoconazole is used topically as a 2% cream for the treatment of tinea corporis, tinea cruris, and tinea pedis caused by *Epidermophyton floccosum*, *Trichophyton mentagrophytes*, or *T. rubrum*. The drug also has been used effectively for the topical treatment of tinea manuum caused by *Trichophyton* and tinea corporis caused by *Microsporum*. Like other imidazole derivatives (e.g., clotrimazole, econazole, miconazole, oxiconazole, sulconazole) and ciclopirox olamine, ketoconazole has an advantage over some other topical antifungal agents (e.g., nystatin, tolnaftate) in the treatment of mixed infections or for empiric treatment pending identification of the causative organism since the drug is active against both dermatophytes and *Candida*.

Tinea corporis and tinea cruris generally can be effectively treated using a topical antifungal; however, an oral antifungal may be necessary if the disease is extensive, dermatophyte folliculitis is present, the infection is chronic or does not respond to topical therapy, or the patient is immunocompromised because of coexisting disease or concomitant therapy. Many clinicians consider topical imidazole-derivative azole antifungals (e.g., clotrimazole, econazole, ketoconazole, miconazole, oxiconazole, sulconazole) or topical allylamine antifungals (e.g., naftifine, terbinafine) the drugs of first choice for the topical treatment of tinea corporis or tinea cruris, although other antifungals (e.g., ciclopirox olamine, butenafine hydrochloride, tolnaftate, undecylenic acid) also can be effective in the treatment of these infections. While topical antifungals usually are effective for the treatment of uncomplicated tinea manuum and tinea pedis, an oral antifungal usually is necessary for the treatment of hyperkeratotic areas on the palms and soles, for chronic moccasin-type (dry-type) tinea pedis, and for the treatment of tinea unguium (onychomycosis).

Clinical studies indicate that ketoconazole 2% cream generally is effective when used once daily for the treatment of tinea corporis, tinea cruris, or tinea pedis. However, in one controlled study, twice-daily application of the cream was more effective than once-daily application for the topical treatment of tinea corporis and tinea cruris. In several controlled studies, ketoconazole 2% cream used twice daily was as effective as clotrimazole 1% cream used twice daily for the treatment of tinea corporis, tinea cruris, or tinea pedis. Ketoconazole 2% cream has been effective in a few patients for the topical treatment of tinea pedis extending beyond interdigital areas (e.g., moccasin-type tinea pedis).

Cutaneous Candidiasis

Ketoconazole is used topically as a 2% cream for the treatment of cutaneous candidiasis caused by *C. albicans*. Like other imidazole derivatives (e.g., clotrimazole, econazole, miconazole, oxiconazole, sulconazole) and ciclopirox olamine, ketoconazole has an advantage over some other topical antifungals (e.g., nystatin, tolnaftate) in the treatment of mixed infections or for empiric treatment pending identification of the causative organism since the drug is active against both dermatophytes and *Candida*.

Clinical studies indicate that ketoconazole 2% cream generally is effective when used once daily for the treatment of cutaneous candidiasis. In several controlled studies, ketoconazole 2% cream used twice daily was as effective as clotrimazole 1% cream used twice daily for the treatment of cutaneous candidiasis.

Pityriasis (Tinea) Versicolor



Ketoconazole is used topically as a 2% cream or 2% shampoo for the treatment of pityriasis (tinea) versicolor, a superficial infection caused by or presumed to be caused by *Malassezia furfur*.

Pityriasis (tinea) versicolor generally can be treated topically with an imidazole-derivative azole antifungal (e.g., clotrimazole, econazole, ketoconazole, miconazole, oxiconazole, sulconazole), an allylamine antifungal (e.g., terbinafine), ciclopirox olamine, or certain other topical therapies (e.g., selenium sulfide 2.5%). However, an oral antifungal (e.g., itraconazole, ketoconazole) may be indicated, with or without a topical agent, in patients who have extensive or severe infections or who fail to respond to or have frequent relapses with topical therapy.

Clinical studies indicate that ketoconazole 2% cream generally is effective when used once daily for the treatment of pityriasis (tinea) versicolor. Safety and efficacy of ketoconazole 2% shampoo for the topical treatment of pityriasis (tinea) versicolor was evaluated in a double-blind, placebo-controlled study in patients with moderately severe, mycologically confirmed infections. A successful response was attained in 73% of those who received a 3-day regimen of once-daily application of 2% ketoconazole shampoo, 69% of those who received a single application of the shampoo, and 5% of those who received placebo; the mycologic clearance rates were 84, 78, and 11%, respectively. The difference in efficacy between the 2 shampoo regimens was not statistically significant.

Seborrheic Dermatitis and Dandruff

Ketoconazole is used topically for the treatment of seborrheic dermatitis, including seborrheic dermatitis of the scalp. Ketoconazole also is used topically for *self-medication* for the reduction of flaking, scaling, and itching associated with dandruff.

Ketoconazole 2% cream is effective when used alone for the topical treatment of seborrheic dermatitis of the face, scalp, chest, or back. The drug has reduced *Malassezia ovalis* (*Pityrosporum ovale*) cell counts in affected treated areas, and has improved manifestations of dermatitis (e.g., scaling, pruritus, erythema).

Ketoconazole 2% foam is used for the treatment of seborrheic dermatitis in immunocompetent adults and children 12 years of age or older. In a phase 3 randomized, double-blind study in adults and children 12 years of age or older with mild, moderate, or severe seborrheic dermatitis involving the scalp, face, chest, or ears, ketoconazole 2% foam twice daily for 4 weeks was more effective than vehicle foam and noninferior to ketoconazole 2% cream. The foam improved manifestations of dermatitis (erythema, scaling, induration).

Ketoconazole 2% gel is used for the treatment of seborrheic dermatitis in immunocompetent adults and children 12 years of age or older. In a phase 3 randomized, double-blind study in adults and children 12 years of age or older with moderate to severe seborrheic dermatitis, ketoconazole 2% gel once daily for 14 days was more effective than gel vehicle and resulted in improvements in manifestations of dermatitis (scaling, erythema, pruritus).

Ketoconazole 1% shampoo is used for *self-medication* to reduce flaking, scaling, and itching associated with dandruff.

Ketoconazole 2% shampoo has been used for the topical treatment of scalp seborrheic dermatitis and dandruff. Following response to treatment, a prophylactic regimen (e.g., once-weekly application of the 2% shampoo) has prevented relapse.

Other Uses

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Ketoconazole 2% cream has been used with good results in combination with a topical corticosteroid (beclomethasone dipropionate or clobetasone butyrate) and an antibacterial agent (fusidate sodium) for the treatment of a variety of dermatoses that frequently involve fungal or bacterial superinfections (e.g., atopic dermatitis, diaper rash, eczema, folliculitis, impetigo, intertrigo, lichenoid dermatitis, psoriasis).

An extemporaneously prepared ophthalmic suspension containing ketoconazole 2% has been used with some success in a limited number of patients for the topical treatment of fungal keratitis caused by *Alternaria*, *Aspergillus*, *Fusarium*, or *Mycelia sterilia*. However, in rabbits, ketoconazole has generally been ineffective for the topical treatment of *Aspergillus fumigatus* keratitis or *C. albicans* corneal infections. *Commercially available ketoconazole cream, foam, gel, and shampoo should not be applied to the eye.*

For other uses of ketoconazole,

Customer Reviews



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