

New Topical Blends Antifungal, Cosmetic and Nail Renewal Agents

This three-in-one formula is available exclusively in physician practices.

BY JOLYNN TUMOLO

Sandal and flip-flop season in Scottsdale, AZ, typically spans 9 or more months of the year. People with unsightly toenails because of onychomycosis or other reasons may feel the discomfort in several ways—self-consciousness over the look and condition of their exposed toes or the burden of covering their feet with socks and shoes when it would otherwise be unnecessary.

During a visit with Kris A. DiNucci, DPM, FACFAS, owner of the Foot and Ankle Center of Arizona in Scott-

Her nails dramatically improved in appearance.—DiNucci

sdale, a woman in her 70s confessed she'd had enough. Oral medication and laser treatment had failed to keep the fungus on her toenails at bay for any length of time. She wanted a longer-term solution.

"For her, she felt as though her feet were always dirty because she could never clear the nails," Dr. DiNucci said. "She was considering removal of the nails permanently."

Instead, Dr. DiNucci suggested Tolcycen[®], a combination antifungal-cosmetic-nail renewal medication his practice had recently begun offering. She agreed, and today her toenails are 75% better.

"Her nails dramatically improved in appearance. She was happy with the results, and now she's fine with not removing the nails," Dr. DiNucci said. "It's nice as a physician to be able to recommend a product that actually works and you can be confident in its use."

A Multifunctional Solution

Launched in January for dispensing in physician practices, Tolcycen is designed to

treat onychomycosis and other cosmetic nail pathologies that have not responded to treatment. The solution contains a mix of ingredients that work together to bring about several aims: tolnaftate 1% and undecylenic acid 25%, to tackle fungal infections; urea, lactic acid and propylene glycol, to soften, thin and lighten discolored nails; and jojoba oil and vitamin E, to moisturize and promote healthy nail growth.

Unlike over-the-counter topical antifungals that use heavy seed oil excipients that can block penetration to the nail, Tolcycen follows the lead of prescription topical antifungals and uses alcohol excipients to effectively penetrate the nail bed, explained Perry Forrester, president of Marlinz Pharma, Houston.



Forrester's relationship with the podiatry profession goes back years—he's the founder of surgical product makers Instratek, Koby Surgical and Metasurg. He launched Marlinz Pharma several years ago with the intent of developing a quality product podiatrists could dispense in their offices.

The development of Tolcycen took 3 years and the input of a team of private pharmaceutical research scientists, Forrester said. Since its launch, over 60,000 units have been distributed to more than 400 physicians. In addition to its unique blend of ingredients, Tolcycen fea-

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New Concepts and Studies

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tures a patented, user-friendly delivery system: a brush-tip applicator that allows for controlled, precise delivery of the solution to the nail, hyponychium and nail folds. A screw-on cap and shut-off valve prevent evaporation of the remaining solution in the tube and eliminate waste.

Noticeable Results

Charles J. Gudas, DPM, owner of Associated Foot Specialists in Charleston, SC, agreed to give Tolcylen a try in his practice in early 2017. He hadn't had much success with

Treatment with Tolcylen comes in at a much lower cost to many patients than a prescription medication would.—Forrester

other local onychomycosis products, but—not a fan of oral medications—he decided to see what Tolcylen could do.

“I was sort of surprised after the initial usage of how many people came back and said, ‘This is working,’ Dr. Gudas said. “It was the first time something like this seemed to work.”

Dr. Gudas estimated that 80% of patients with toenail fungus who used Tolcylen experienced significant improvement 6-12 weeks after initiating treatment. Among them was an attorney who, while he enjoyed playing golf, didn't appreciate the attention his affected toenail garnered in the locker room.

Informal results from a retrospective case study of 5 physician practices in California and Florida overseeing the treatment of 1,100 patients who used Tolcylen identified more than 90% patient satisfaction after 60 days' use, according to Marlinz Pharma. Additionally, a 2011 placebo-controlled study in Sweden that focused on 3 of the cosmetic ingredients in Tolcylen—urea, lactic acid and propylene glycol—found 77% of patients experienced marked improvement in nail appearance within 2 weeks. By 8 weeks, appearance improved for 92% of patients.

Skin irritation occurs in less than 1% of patients and can be resolved with limited or discontinued use, according to the company. A tube of the solution runs about \$60 for patients and, depending on how many toes are treated, typically lasts 3-6 months. When all is said and done, treatment with Tolcylen comes in at a much lower cost to many patients than a prescription medication would, Forrester said.

“Oral prescription antifungal medications require blood tests because of potential harmful side effects,” he explained. “Topical prescription antifungal medications require testing of the nails before insurance companies will consider coverage. Even with a positive test result, the patient's copay can still be very high. Not only does that result in an expensive treatment option, but neither the oral or the topical prescription antifungal medications will improve the appearance of the nail rapidly. Tolcylen is significantly less expensive to the patient and provides noticeable results in a short period of time.”

Growing Demand

To date, Peter Redko, DPM, of North Bay Foot and Ankle Center, Petaluma, CA, has dispensed more than 700 tubes of Tolcylen. The vast majority of patients, he said, have been satisfied with the results.

“Patients are amazed at how well and quickly it starts to clear up their nails,” Dr. Redko said. “They are ecstatic when they show me a healthy nail growing out from under the cuticle.”

Dr. DiNucci suggests patients take monthly pictures to track the effect of Tolcylen over time.

“Although I have some patients who have not completely cleared their nails,” Dr. DiNucci said, “almost every patient gets better.”

Certain steps can increase the likelihood of success. In more severe cases, Dr. DiNucci combines Tolcylen with prescription oral medications or laser treatments. Dr. Gudas pointed out the importance of educating patients on how to prevent re-exposure to the fungus during treatment.

To augment treatment and prevent cross-contamination, Marlinz Pharma also offers Tolcylen Antifungal Skin Cream and Tolcylen Antifungal, Antimicrobial Shoe Spray. The active ingredient in the skin cream is tolnaftate 1%, which works to treat and prevent recurrence of athlete's foot, according to the company, while a handful of cosmetic agents (urea, undecylenic acid, lactic acid, propylene glycol and tea tree oil) aim to improve skin appearance and health. The shoe spray is designed to kill spores on contact, the company said, and is formulated with undecylenic acid and active silver ions that can penetrate leather and insoles to keep footwear microbe-free over time. Patients can purchase all 3 Tolcylen products for approximately \$120 at Dr. Gudas' clinic.

The cash-only product line serves to benefit private practices in addition to patients, although Dr. Gudas made it clear he wouldn't recommend Tolcylen if it didn't generate solid clinical results. That said, avoiding the hassle of insurance precertification—only to discover a patient can't afford the copay—saves work and time, he said. Moreover, in a health care climate that has independent specialists of all types looking for ways to generate additional cash revenue, the podiatrist appreciates what Tolcylen offers. According to Marlinz Pharma, a busy solo practitioner may go through more than 100 Tolcylen units per month at an average \$40 profit per unit. Larger practices may sell double or triple that amount.

“Our problem is, we tend to run out of it, rapidly,” Dr. Gudas said. While podiatrists require an office visit before initial dispensing, returning patients can return to purchase additional product without an appointment. “You have to anticipate that ahead of time when managing your inventory,” he advised.

“Like I said, I was skeptical in the beginning, but I'm converted now,” he added. “It's a good product.” **PM**



Jolynn Tumolo is a freelance writer in Morgantown, PA.