Novel Lacquer Bests Penlac for Onychomycosis

BY BRUCE JANCIN

BERLIN — A formulation of 8% ciclopirox-medicated nail lacquer for onychomycosis significantly outperformed a commercially available version in a 467-patient, 60-week randomized trial.

The product, ciclopirox hydroxypropyl-chitosan nail lacquer (CicloPol, Polchem, or P-3051), had an overall 119% greater microbicidal cure rate compared with the commercially available 8% ciclopirox monooester (Penlac, Sanofi-Aventis).

Penlac significantly outperformed placebo, as expected based on earlier product registration studies in Europe, Dr. Federico Mailland reported at the annual congress of the European Academy of Dermatology and Venereology (EADV). CicloPol is currently only available in Europe; Penlac is available in Europe and the United States.

The multicenter trial involved patients with toenail onychomycosis of varying severity who were randomized 2:1 to P-3051, Penlac, or placebo. They treated themselves for 48 weeks and were followed for another 12 weeks (J Eur Acad Dermatol Venereol. 2009;23:773-81).

The results varied markedly depending on baseline severity. Mild disease was defined as baseline involvement of less than 25% of the toenail, and severe as greater than 65% involvement.

The 68-week cure rate, defined as negative mycology by both KOH (potassium hydroxide) and culture, along with a 100% healthy-appearing nail, was 50% in patients with P-3051-treated mild disease and 0% with Penlac. For patients with moderate severity, the response rates were 12.3% with P-3051 and 7.1% for Penlac. And for severe disease, the cure rates were 5.7% and 3.6%, respectively, said Dr. Mailland of Polchem SA in Lugano, Switzerland (manufacturer of CicloPol).

The same pattern was seen with responder rates as defined by negative mycology and at least a 90% healthy-appearing nail. For patients with baseline mild fungal disease, the 68-week responder rates were 62.5% with P-3051 and 40% with Penlac. For moderate disease, responder rates were 31.6% and 17.2%. For severe disease, response rates were 11.4% with P-3051 and 3.6% with Penlac.

The new topical nail lacquer is an attractive alternative to oral treatment, even in severely affected patients, provided they are prepared for long-term therapy, said Dr. Mailland.

Adapalene Advised for Mild, Moderate Acne

WASHINGTON — The newer topical retinoid adapalene is often the best front-line agent for the management of mild to moderate acne because it can be applied along with benzoyl peroxide, according to Dr. Richard J. Antaya. Adapalene (Diffren) is “a much more stable molecule, so you can apply it with other medications like benzoyl peroxide,” said Dr. Antaya, director of pediatric dermatology at Yale University in New Haven, Conn. “Ret-A gets broken down much more easily.”

Although a topical retinoid alone is effective for mild acne that is primarily comedonal, benzoyl peroxide (a topical antibacterial) should be added when the acne is papulopustular, he explained at the annual meeting of the American Academy of Pediatrics. A topical antibiotic also should be part of the regimen if the acne is more severe at presentation or if it does not improve in 6-12 weeks of treatment with a retinoid and benzoyl peroxide.

Moisturizers are a critical part of acne management since all medications cause some degree of erythema, drying, or peeling. “With Tazorac [tazarotene], an other-new generation topical retinoid, because it’s so irritating, we’ve actually realized that if you put moisturizer on before the Tazorac, it actually slows the [drug’s] absorption and softens the blow so you’re less bothered,” said Dr. Antaya.

He said that he had no financial relationships in the past year with any manufacturers of these products.

—Christine Kilgore