



# Topical Psoriasis Therapies: An Update



The latest research offers insights on the benefits and utility of topical treatment.

BY LEON H. KIRCIK, MD

>> Psoriasis is a disease of systemic inflammation. While this understanding of the disease has opened new avenues of treatment and led to important insights into the long-term management of patients with moderate to severe disease, the reality of clinical practice is that many patients have mild to moderate disease and can be effectively treated with topical therapy. Research continues to show that the majority of psoriasis patients in the US receive a prescription for topical therapy. For 95 percent of adult patients in the US a topical therapy is the first-line therapy used, and 83 percent remain on topicals only.<sup>1</sup>

Over the past few months, a few developments have emerged in the literature that may impact the patient experience. Here's a closer look.

## HALOBETASOL/TAZAROTENE LOTION

Tazarotene has long been used for the management of psoriasis, although the drug is known to cause local skin irritation. Concomitant use of topical corticosteroids has been shown beneficial to help relieve this irritation while conferring anti-inflammatory effects. An investigational topical fixed combination of halobetasol 0.01%/tazarotene 0.045% (HP/TAZ, Duobrii, Ortho Dermatologics) lotion has shown clinical efficacy and has been approved for topical treatment.

Tazarotene can be a challenging molecule to formulate. The unique lotion base for Duobrii is notable for facilitating the formulation of tazarotene and halobetasol in a single vehicle that assures the two agents remain active.

In two studies designed to assess the potential for skin irritation and contact sensitization of HP/TAZ lotion, there was no evidence of contact sensitization, and minimal skin irritation.<sup>2</sup> In a Phase 2 study to assess the efficacy and safety of once-daily HP/TAZ lotion, 154 subjects were randomized

2:2:1 to undergo treatment with HP/TAZ lotion, halobetasol propionate 0.05% cream, or vehicle, applied topically once daily for two weeks. HP/TAZ lotion was significantly more effective than vehicle and was comparable to halobetasol propionate 0.05% cream in reducing erythema, plaque elevation, and scaling.<sup>3</sup>

In two Phase 3 prospective, multi-center, randomized, double-blind clinical trials with 418 subjects 18 years or older with moderate to severe plaque psoriasis, Duobrii was consistently more effective than vehicle in achieving treatment success, demonstrating statistically significant superiority by week 4 (in Study 1) and week 2 (in Study 2). At week 8, 36 percent and 45 percent of treated patients, respectively, had achieved the primary efficacy outcome, compared to seven percent and 13 percent for vehicle.

## HALOBETASOL PROPIONATE LOTION

Corticosteroids have been a cornerstone of topical psoriasis treatment for decades and remain important in the acute treatment phase. Relatively new to the market is Bryhali Lotion (halobetasol propionate 0.01%, Ortho Dermatologics), a first of its kind lotion formulation for the active drug. In two multicenter, randomized, double-blind,

More than 80 percent of psoriasis patients are treated with topical therapy. Topical fixed combination halobetasol 0.01%/tazarotene 0.045% lotion and halobetasol lotion 0.01% provide new options for patients, while data support the benefit of the established treatment, calcipotriene 0.005% and betamethasone dipropionate 0.064% topical suspension.

thebottomline

**“ The unique lotion base for Duobrii is notable for facilitating the formulation of tazarotene and halobetasol in a single vehicle that assures the two agents remain active.”**

vehicle-controlled Phase 3 studies (n=430), Bryhali was shown to be both safe and effective; active treatment was superior to vehicle at week 2.

Subjects had up to 12 percent Body Surface Area (BSA) involvement at baseline. Treatment was shown to reduce psoriasis signs and symptoms, reduce BSA involvement, and improve quality of life. Patients applied treatment once daily for eight weeks. Through the treatment period and four-week follow-up, treatment was well-tolerated with no treatment-related adverse events (AEs) greater than one percent.<sup>4</sup>

The availability of a lotion formulation of a topical corticosteroid provides a potentially useful vehicle option for patients, especially those applying medication to larger surface areas or on hairy skin. In contrast to thick creams or ointments, the lotion may be efficiently massaged into the skin without leaving a residue. Use of the topical lotion formulation was associated with improved epidermal barrier function and moisture retention and a documented reduction in trans-epidermal water loss, relative to untreated skin.

### **CALCIPOTRIENE/BETAMETHASONE**

Calcipotriene 0.005% and betamethasone dipropionate 0.064% topical suspension (Taclonex TS, Leo Pharma) has emerged as a useful treatment option for many patients with psoriasis, especially those with scalp involvement. A recent study indicates that use of the topical combination suspension was not associated with significant decreases in epidermal or dermal thickness, whereas treatment with betamethasone lotion resulted in significant decreases in epidermal thickness and dermal thickness.<sup>5</sup> This was the first study to demonstrate that the fixed combination was associated with reduced skin thinning relative to corticosteroid alone.

The fixed combination suspension is especially suited to treatment of the hair-bearing scalp. However, the suspension can be used with ease on other areas of the body, as well. Therefore, patients with both scalp psoriasis and involvement of other body sites may find the formulation

useful. A retrospective analysis found that patients using multiple topical medications had 48 percent more outpatient visits as compared with those who used calcipotriene 0.005% and betamethasone dipropionate 0.064% topical suspension, after controlling for baseline covariates. They also had significantly higher psoriasis-related healthcare costs and twice the odds of using systemic agents as compared to patients using the suspension only.<sup>6</sup>

Enstilar Foam (Leo Pharma) is a topical foam formulation of calcipotriene 0.005% and betamethasone dipropionate 0.064%. “Real world” data reported last year from 105 patients with 177 active psoriatic lesions show that use of calcipotriene 0.005% and betamethasone dipropionate 0.064% foam once daily improved psoriasis severity and reduced itch, consistent with clinical trial data.<sup>7</sup>

A pilot study that assessed therapeutic response when calcipotriene 0.005% and betamethasone dipropionate 0.064% foam is used for elbows and knees found treatment effective, with good tolerability.<sup>8</sup>

Limited research has assessed the impact of topical treatment on pain associated with psoriasis, however, in a four-week study of calcipotriene 0.005%/betamethasone dipropionate 0.064% foam, the mean intensity score of skin pain decreased from 7.6 at baseline to 1.3. Among skin pain qualities, intense, sensible, aching, and unpleasant showed the highest rates of reduction.<sup>9</sup> ■

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