Halobetasol 0.01% Lotion in the Treatment of Moderate-to-Severe Plaque Psoriasis of the Lower Extremities

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SYNOPSIS
Psoriasis is a chronic, immune-mediated disease that varies widely in its clinical expression.
Topical corticosteroids are the mainstay of treatment in psoriasis, but long-term safety remains a concern, limiting use, and posttreatment flare-up is common.
While psoriasis commonly affects lower extremities, treatment can be more problematic, and duration of treatment lengthened.

Recent phase 3 clinical data have demonstrated that halobetasol propionate 0.01% lotion (Byhal® Ortho Dermatologics, Bridgewater, NJ) was significantly more effective than vehicle after 8 weeks of treatment in patients with moderate-to-severe localized plaque psoriasis, though efficacy in specific locations has not been reported.

OBJECTIVE
To investigate the efficacy of once-daily HP 0.01% lotion versus vehicle in patients with moderate-to-severe plaque psoriasis at target lesion.

METHODS
Study Design
Data from two phase 3, multicenter, randomized, double-blind studies of patients with moderate-to-severe plaque psoriasis were pooled.
Participants were randomized (2:1) to receive HP 0.01% lotion or vehicle once-daily for 8 weeks, with a 4-week posttreatment follow-up.

At baseline, participants were required to have Investigator Global Assessment (IGA) score of 3 or 4 at target lesion and could not have a score of 0 or 1 in any one of the signs (erythema, plaque elevation, and scaling [5 point scale; 0=clear and 4=severe]), a sum of at least 8, and 3% to 12% Body Surface Area (BSA) involvement.

A post hoc analysis was conducted in a subset of patients with plaque psoriasis of the lower extremities, with a target lesion on the leg.

- For the target lesion, participants needed a score of ≥2 for at least 2 of 3 signs of psoriasis (erythema, plaque elevation, and scaling [5-point scale; 0=clear and 4=severe]), a sum of ≥8, and could not have a score of 0 or 1 in any one of the signs.
- Target could not be on areas covering bony prominences (ie, knees); however, overall psoriasis assessment (IGA and BSA) did not exclude the lower extremities.

In these studies, Cerave® hydrating cleanser and Cerave® moisturizing lotion (L’Oreal, NY) were provided as needed for optimal moisturization/clearing of the skin.

Efficacy Assessments
Treatment success (≥2-grade improvement from baseline in IGA score and a score of ‘clear’ or ‘almost clear’) in 37.7% of patients treated with HP 0.01% lotion compared with 7.2% treated with vehicle (P=0.001; Figure 3).

HP-treated patients had a 34.2% mean reduction from baseline in overall BSA compared with a 3.7% reduction in vehicle-treated patients (P=0.001; Figure 4).

CONCLUSION
Halobetasol propionate 0.01% lotion provided significant efficacy versus vehicle and clinically relevant improvements in QoL following 8 weeks of therapy in patients where the leg was identified as the target lesion.

REFERENCES

AUTHOR DISCLOSURES
Dr. Neal Bhatia has received honoraria from Ferndale Laboratories, Inc., Promius Pharma, LLC, Novartis, Allergan, Biofrontera AG, IntraDerm Pharmaceuticals, Almirall, Sun Biologics, Inc., Amgen, and Amgen Ireland B"R., and research funding from Regeneron, Actavis, Biofrontera AG, Dermira, Glenmark Generics Inc., Sanofi/Regeneron, Actavis, Agios Pharmaceuticals, Inc., and Allergan. Dr. Tracey Vlahovic has received honoraria from Ferndale Laboratories, Inc., Promius Pharma, LLC, Novartis, Allergan, Biofrontera AG, IntraDerm Pharmaceuticals, Almirall, and Sun Biologics, Inc., and research funding from Regeneron, Actavis, Agios Pharmaceuticals, Inc., and Allergan.

Figure 2 illustrates treatment success with HP 0.01% lotion in the leg target lesion.

Figure 3: Overall Treatment Success on IGA Assessment of Disease Severity

Figure 4: Mean Percent Reduction in Overall Body Surface Area (BSA)