# Use of Combination Halobetasol Propionate/Tazarotene Lotion in Difficult-to-Treat Psoriasis and TNF-α Mechanism of Action

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## OBJECTIVE

- **To review previously published results from open-label studies of HP/TAZ in palmoplantar psoriasis and scalp psoriasis in the context of reduction of proinflammatory mediators such as TNF-α**

## CONCLUSION

- **The inhibition of TNF-α by HP/TAZ could potentially contribute to the effectiveness of HP/TAZ in psoriasis lesions involving difficult-to-treat areas**

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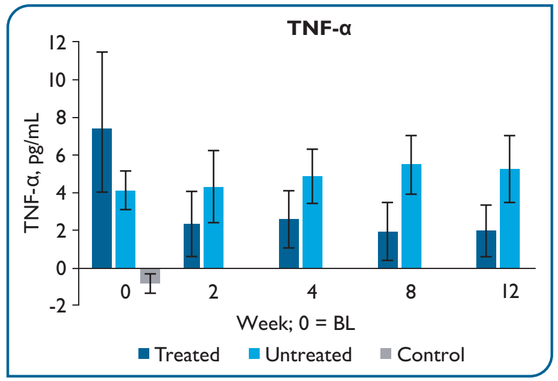
## SYNOPSIS

- Tumor necrosis factor α (TNF-α) plays a key role in the pathogenesis of psoriasis and is a target of systemic therapies[1]
  - Systemic TNF-α inhibitors have been shown to be efficacious against difficult-to-treat areas of psoriasis[2]
- A recent study showed that fixed-combination halobetasol propionate 0.01%/tazarotene 0.045% lotion (HP/TAZ) substantially reduced TNF-α levels in psoriatic plaques at weeks 2 through 12 of treatment compared with levels in untreated plaques (Figure 1)[3]

**Figure 1.** TNF-α levels in plaques treated with HP/TAZ vs untreated plaques across 12 weeks.[3]




TNF-α, tumor necrosis factor alpha.

- The additive effect of HP and TAZ on reduction of proinflammatory mediators such as TNF-α[4] may improve outcomes in difficult-to-treat areas, such as the palms, soles of the feet, and scalp
  - The combined benefits of HP/TAZ could result from nonoverlapping immunogenetic mechanisms of HP and TAZ[4]
  - Additionally, TAZ may mitigate the risk of skin atrophy associated with prolonged topical corticosteroid use[4]

## METHODS

### Palmoplantar Psoriasis Study[5]

- In an investigator-initiated, open-label study, adult participants with moderate-to-severe palmoplantar psoriasis (N=17) were treated once daily with HP/TAZ for 24 weeks
  - Psoriasis severity was assessed by the Palmoplantar Physician Global Assessment (ppPGA), with a score of 0 indicating "clear" and a score of 5 indicating "severe"
  - ppPGA was assessed at baseline and again at week 24

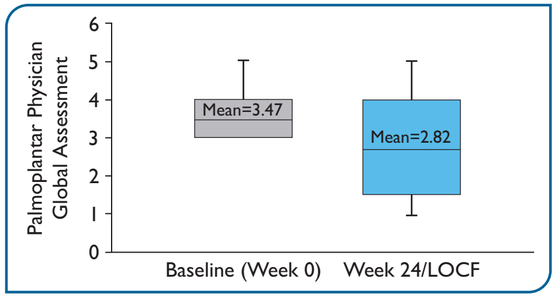
### Scalp Psoriasis Study[6]

- In a single-center, open-label pilot study, adult participants who had moderate-to-severe psoriasis with scalp involvement (N=21) applied HP/TAZ once daily for 8 weeks and were followed for 4 weeks posttreatment (week 12; N=20)
- The primary endpoint was proportion of participants with an Investigator's Global Assessment (IGA) score of 0 or 1 (clear or almost clear) at week 8
- Other outcomes included 75%/90%/100% improvement in Psoriasis Scalp Severity Index (PSSI 75/90/100, respectively) and scalp IGA (sIGA) improvement

## RESULTS

- In the palmoplantar study, mean ppPGA scores improved significantly with HP/TAZ treatment from baseline to week 24 ($P$=0.0165; Figure 2)[5]

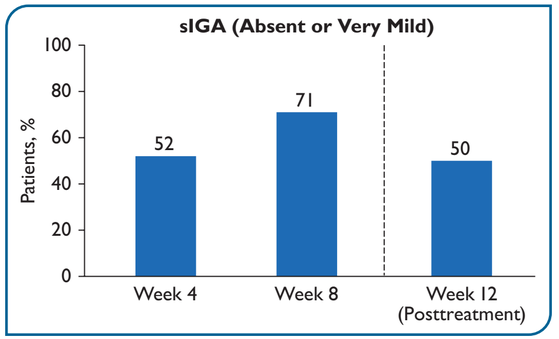
**Figure 2.** Improvements in Palmoplantar Physician Global Assessment from baseline to week 24 in patients receiving HP/TAZ.




HP/TAZ, halobetasol propionate 0.01% and tazarotene 0.045%; LOCF, last observation carried forward.[5]

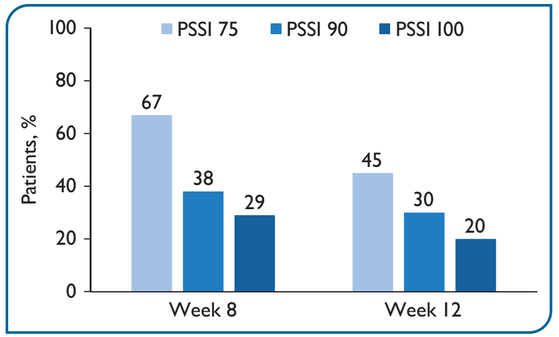
- At week 8 in the scalp psoriasis study[6]:
  - 10/21 patients (48%) achieved a score of IGA 0 or 1
  - 15/21 patients (>70%) achieved an sIGA score of 0 or 1, and 50% maintained these scores at week 12 (Figure 3)
  - Nearly one-third of patients (29%) had sIGA 0, and 20% maintained sIGA 0 at week 12
- Significant improvements from baseline in PSSI 75 rates were observed at weeks 4, 8, and 12 ($P$≤0.0005 for all)
- Rates of PSSI 75/90/100 were maintained from week 8 to 12 (Figure 4)
  - PSSI 75: 67% of patients achieved PSSI 75 at week 8, with 45% maintaining at week 12
  - PSSI 90: 38% of patients achieved PSSI 90, with 30% maintaining at week 12
  - PSSI 100: 29% of patients achieved PSSI 100, with 20% maintaining at week 12

**Figure 3.** Percent of patients receiving HP/TAZ who achieved sIGA clear or almost clear.




HP/TAZ, halobetasol propionate 0.01% and tazarotene 0.045%; sIGA, scalp Investigator's Global Assessment.[6]

**Figure 4.** Percent of patients achieving PSSI 75, 90, and 100 at conclusion of HP/TAZ therapy (8 weeks) and at 4-week follow-up (12 weeks).




HP/TAZ, halobetasol propionate 0.01% and tazarotene 0.045%; PSSI, Psoriasis Scalp Severity Index.[6]

- In both studies, HP/TAZ was well tolerated[5,6]
  - There were no reported instances of skin atrophy, striae, telangiectasia, or folliculitis in the scalp psoriasis study
  - Only application site dermatitis (n=3) was reported in the palmoplantar psoriasis study

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**References: 1.** Chima and Lebwohl. *Semin Cutan Med Surg.* 2018;37:134-142. **2.** Lanna et al. *Dermatol Ther.* 2020;33:e13374. **3.** Draelos et al. Presented at: FCDC 42nd Annual Fall Clinical Dermatology Conference; October 20-23, 2022; Virtual and Las Vegas, NV. **4.** Lebwohl et al. *Dermatol Ther (Heidelb).* 2021;11:1157-1174. **5.** Campbell et al. Presented at: American Academy of Dermatology Annual Meeting; March 25-29, 2022; Boston, MA. **6.** Ozyurekoglu and Kircik. *J Drugs Dermatol.* 2021;20:1191-1194.