



Influence of Season on Efficacy and Tolerability of Tazarotene 0.045% Lotion for the Treatment of Acne

by JERRY TAN, MD; ZOE D. DRAELOS, MD; MELINDA J. GOODERHAM, MSc, MD; ANDREW F. ALEXIS, MD, MPH; EMMY GRABER, MD, MBA; JONETTE KERI, MD, PhD; HEATHER C. WOOLERY-LLOYD, MD; JULIE C. HARPER, MD; FRAN E. COOK-BOLDEN, MD; ADARSH KONDA, PharmD; and EMIL A. TANGHETTI, MD

Dr. Tan is with the Schulich School of Medicine and Dentistry at Western University in Ontario, Canada. Dr. Draelos is with Dermatology Consulting Services, PLLC in High Point, North Carolina. Dr. Gooderham is with Queens University in Ontario, Canada and SKIN Centre for Dermatology and Probiy Medical Research in Ontario, Canada. Drs. Alexis and Cook-Bolden are with Weill Cornell Medical College in New York, New York. Additionally, Dr. Cook-Bolden is with Fran E. Cook-Bolden, MD, PLLC in New York, New York. Dr. Graber is with The Dermatology Institute of Boston in Boston, Massachusetts and Northeastern University in Boston, Massachusetts. Drs. Keri and Woolery-Lloyd are with the University of Miami's Miller School of Medicine in Miami, Florida. Dr. Harper is with the Dermatology and Skin Care Center of Birmingham in Birmingham, Alabama. Dr. Konda is with Ortho Dermatologics, a division of Bausch Health US, LCC, in Bridgewater, New Jersey. Dr. Tanghetti is with the Center for Dermatology and Laser Surgery in Sacramento, California.

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OBJECTIVE: The condition of the skin can vary due to weather fluctuations. Therefore, this *post-hoc* analysis evaluated efficacy and safety of tazarotene 0.045% lotion in warmer versus colder months. **METHODS:** In two Phase III, double-blind, 12-week studies, participants aged nine years or older with moderate-to-severe acne were randomized 1:1 to once-daily tazarotene or vehicle lotion. The pooled population (N=1,614) was stratified by randomization date (warmer=May to September; colder=October to April). Evaluations included inflammatory/noninflammatory lesion counts, treatment success, adverse events, and safety/tolerability. **RESULTS:** Tazarotene 0.045% lotion was similarly efficacious over colder and warmer months. Compared with vehicle, tazarotene demonstrated significantly greater least-squares mean absolute reductions from baseline to Week 12 in inflammatory (colder/warmer tazarotene vs. vehicle: –16.6/–15.8 vs. –13.2/–12.9) and noninflammatory lesions (–23.2/–22.6 vs. –17.5/–15.1); treatment success rates were also significantly higher (30.1/30.8% vs. 18.2/17.6%) ($P<0.001$, all). No strong seasonal trends in safety were observed, though tazarotene led to slightly more discontinuations (3.4% vs. 1.9%) and related adverse events (12.0% vs. 10.3%) in colder versus warmer months. Transient increases in scaling, erythema, and itching at Weeks 2 to 8 of tazarotene treatment were slightly higher in colder versus warmer months but returned to baseline/improved by Week 12. **LIMITATIONS:** Geographical variation across study sites can lead to varying temperatures and humidity within the same months. **CONCLUSION:** Tazarotene 0.045% lotion was efficacious and well tolerated for acne treatment, regardless of season. Year-round tolerability of tazarotene 0.045% lotion may be due to its lower tazarotene concentration and polymeric emulsion technology, which simultaneously delivers moisturizers/humectants/emollients to skin. **KEYWORDS:** Retinoid, acne, season, weather, tolerability

Although retinoids, such as tazarotene, are a mainstay of acne treatment, the associated cutaneous irritation and drying—especially with older formulations of tazarotene gel and cream^{1,2}—could lead to poor adherence and negatively impact treatment success.^{3,4} Moreover, the skin's susceptibility to irritation can vary by season due to fluctuations in environmental factors like temperature and humidity. In healthy adults, facial skin shows increased redness^{5–8} and scaliness,^{5,9} and a possible decrease in hydration^{6,10–13} in the winter months compared to summer. Further, skin lipid content, which is essential

for maintaining skin barrier function, is reduced in colder weather.^{11,14} Accordingly, transepidermal water loss is greater,^{5–7,13} and response to skin irritants is exacerbated.¹⁵ While these seasonal skin changes could influence the cutaneous tolerability of topical retinoids, to our knowledge, there are no published studies examining if seasonal variation impacts the tolerability or efficacy of topical retinoids for acne treatment.

To reduce irritation, a polymeric emulsion lotion formulation with a lower concentration of tazarotene (0.045%) and with hydrating excipients was developed, which evenly distributes tazarotene on the surface of the

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CORRESPONDENCE: Jerry Tan, MD; Email: jerrytan1230@outlook.com