Vehicle Formulation Impacts Tolerability and Patient Preference: Comparison of Tretinoin Branded Lotion and Generic Cream

Zoe D Draelos, MD; Amber Blair, PA-C; Emil A Tanghetti, MD

Dermatology Consulting Services, PLLC, High Point, NC; *Dermatology, Laser & Vein Specialists of the Carolinas, Charlotte, NC; ‡Center for Dermatology and Laser Surgery, Sacramento, CA

SYNOPSIS
Vehicle design and optimization of topical formulations are critical to the drug-development process, as product vehicle and active/matrix ingredients can contribute to drug tolerability/lucency and patient preference/adherence. Rетinoids are a mainstay of acne treatment, though topical retinoids—such as tretinoin—can be associated with significant cutaneous irritation and drying, which can lead to poor adherence. To mitigate these issues, tretinoin 0.05% lotion (Altreno) was formulated using a polymeric honeycomb matrix, which allows for efficient and uniform delivery of micronized tretinoin and moisturizing/hydrating ingredients. (Figure 5)

Branded topical acne therapies, however, are often substituted at the pharmacy for a generic version, without accounting for the physiological differences between branded and generic formulation and the potential impact of this substitution. (Figure 6, open bars)

METHODS
In this single-center, double-blinded, split-face study, females with acne aged ≤18 years were randomized to apply tretinoin lotion or generic cream once daily to the right or left cheek for 2 weeks. (Figure 2, closed bars)

Assessments were conducted immediately after first use and after two weeks of treatment with each treatment.

The investigators assessed erythema, scaling, dryness, smoothness, softness, smoothness, radiance, and brightness on a 5-point scale (0=none, 1=minimal, 2=mild, 3=moderate, 4=severe).

Participants completed a 16-item facial sensory questionnaire assessing their impressions of the products and their skin on a 9-point scale (1=agree completely, 9=disagree completely) for each side of their face.

CONCLUSIONS
In this split-face study, tretinoin 0.05% lotion led to significantly improved tolerability and patient preference, underscoring the potential negative impact of generic switching at the pharmacy.

Given the established impact of tolerability and patient preference on drug adherence and treatment success, this further underscores the potential negative effect of generic switching at the pharmacy.

REFERENCES

AUTHOR DISCLOSURES
Zoe D Draelos receives consulting fees from Ortho Dermatologics to conduct the research presented in this manuscript. Amber Blair has served as speaker for Novartis, Ortho Dermatologics, Sanofi, Lilly, Galderma, and Amgen. Emil A Tanghetti has served as a consultant to clinical data management firms, Ortho Dermatologics, and Galderma, and is a stockholder for Accure.

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