



ACNE, ROSACEA, AND RELATED DISORDERS (INCLUDING HIDRADENITIS SUPPURATIVA)

PREVENTION AND REDUCTION OF ATROPHIC ACNE SCARS IN MODERATE TO SEVERE ACNE SUBJECTS TREATED WITH TOPICAL ADAPALENE 0.3%/BENZOYL PEROXIDE 2.5% GEL

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Introduction: Atrophic scars are a common sequelae of acne; however, few clinical trials have investigated topical acne treatment and scarring.

Objective: Evaluate adapalene 0.3%/benzoyl peroxide 2.5% (A0.3/BPO2.5) gel vs vehicle gel and atrophic acne scar formation risk in subjects with moderate/severe acne vulgaris (AV).

Methods: Multicenter, randomized, investigator-blinded, vehicle-controlled, intra-individual comparison (right vs left half-face) in subjects (16 to 35 y) with moderate/severe facial AV (Investigator's Global Assessment [IGA] score 3/4; ≥ 25 inflammatory lesions; ≥ 10 atrophic acne scars). Treatment: 24 weeks of A0.3/BPO2.5 gel or vehicle gel (each half-face) and skin care (both sides). Assessments: investigator atrophic acne scar count, Scar Global Assessment (SGA), acne lesion count, IGA, subject self-evaluation questionnaires, local tolerability, and safety.

Results: Of 67 subjects randomized, 54 (80.6%) completed the study. At baseline, most subjects had moderate acne (92.5%) with mild (62.7%) or moderate scars (29.9%). A0.3/BPO2.5 gel was significantly superior in reducing acne scar counts from W1 (all $p < .01$). By W24, total atrophic scar count had decreased 15.5% for A0.3/BPO2.5 gel vs an increase of 14.4% for vehicle (9.5 scars A0.3/BPO2.5 vs 13.3 vehicle per half-face, $p < .0001$). SGA clear/almost clear percentage at W24 was 32.9% for A0.3/BPO2.5 gel vs. 16.4% vehicle ($p < .01$). Acne lesion reduction was significantly superior for A0.3/BPO2.5 gel





vs. vehicle (all study visits). The median % change in inflammatory acne lesions at W24 was [?]86.7% for A0.3/BPO2.5 vs. [?]57.9% vehicle ($p < .0001$). Significantly more A0.3/BPO2.5 gel subjects were IGA clear/almost clear after 24 weeks (64.2% vs. 19.4% vehicle, $p < .0001$). Treatment[?]related AEs were reported by 20.9% subjects on the A0.3/BPO2.5 side vs. 9% vehicle side, most commonly skin irritation (14.9% vs. 6% respectively).

Conclusions: Topical A0.3/BPO2.5 gel demonstrated early onset of effect, and after 24 weeks of treatment, significantly fewer atrophic acne scars and acne lesions were observed compared to vehicle treatment.

