



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

RESULTS FROM A MULTI-CENTRE, RANDOMIZED, DOUBLE-BLIND, AND VEHICLE CONTROLLED STUDY (PERFECT 2) TO ASSESS THE EFFICACY AND SAFETY OF TRIFAROTENE 50µG/G CREAM IN SUBJECTS WITH MODERATE FACIAL AND TRUNC

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Introduction: Trifarotene is the first in class highly selective topical retinoid.

Objectives: to assess its efficacy and safety of trifarotene in acne of the face and trunk.

Materials and Methods: This multi-centre, randomized, double-blind, vehicle controlled, 12-week Phase 3 study investigated trifarotene once daily in subjects of at least 9 years of age and with moderate facial acne and truncal acne. Efficacy endpoints were the Investigator- and Physician Global Assessment (IGA and PGA) success rates for face and trunk respectively, and absolute inflammatory and non-inflammatory lesion count change from Baseline at Week 12 on both face and trunk. Safety was assessed through adverse events, local tolerance (erythema, scaling, dryness and stinging/burning), vital signs and routine laboratory testing.





Results: In total, 1212 subjects were recruited. Overall, 602 subjects were treated with trifarotene and 610 with the vehicle.

IGA and PGA success and change in absolute lesion counts were significantly ($p < 0.001$) in favour of Trifarotene. At Week 12, the IGA success rates with trifarotene and the vehicle were 42.3% and 25.7%, respectively. The facial inflammatory lesion count change was -24.2 with trifarotene and -18.7 with the vehicle and -30.1 vs -21.6 for non-inflammatory lesions, respectively. PGA success rates with trifarotene and the vehicle were 42.6% and 29.9%, respectively. The truncal inflammatory lesion count change was -25.5 with trifarotene vs. -19.8 with the vehicle; the non-inflammatory lesion count change was -25.9 with trifarotene vs. -20.8 with the vehicle.

Local tolerability signs and symptoms related to trifarotene were assessed mostly mild or moderate and transient. Most treatment emergent adverse events (TEAEs) related to trifarotene occurred at the application site.

Conclusions: Trifarotene 50µg/g cream is effective and safe in the treatment of moderate acne on the face and trunk. It has an acceptable and manageable local tolerability profile when applied to large body surface areas.

