



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

A MULTI-PRONG APPROACH TO ACNE SIGNIFICANTLY REDUCED FACIAL LESIONS AFTER A 12-WEEK TREATMENT

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Background: The pathogenesis of acne is complex, with strong evidence supporting the involvement of sebaceous hyperplasia, follicular hyperkeratinization, bacterial hypercolonization, and inflammation. A multi-prong approach was used to design a formulation to address these components and combat acne.

Objective: To determine if repeated use of a multi-prong formula would reduce the overall lesion count in a population with acne.

Materials and Methods: Subjects were randomized among two balanced cells stratified by gender and degree/type of acne. One cell received the multi-prong formula and the other received a benchmark formula. Subjects applied a thin layer of treatment to entire face either twice a day (multi-prong formula group) or once daily in the evening (benchmark group). The 224 subjects that completed the study were evaluated at qualification, baseline, week 1, week 4, week 6, and week 12 by a Board Certified Dermatologist based on lesion count and overall global assessment.

Results: At week 12, both treatments significantly reduced the total lesion count vs. baseline, but there was no significant difference between treatments with respect to lesion counts or Investigator's Global Assessment. Using a non-inferiority margin of 10%, the multi-prong formula was found non-inferior to the benchmark.

Conclusion: Based on these results, our test material was found to significantly reduce acne lesion count and performed as well as a benchmark control material after 12 weeks of treatment.

