Efficacy and Tolerance of a 3-Step Acne System Containing a Novel Solubilized Benzoyl Peroxide/Clindamycin Combination Product: An Investigator-Blind, Randomized, Parallel-Group Study

INTRODUCTION

Benzoyl peroxide (BPO) is poorly soluble and formulations typically contain insoluble BPO macromolecules which trap much of the BPO in the interior of the crystals, thus reducing its bioavailability. In addition, the macromolecules may have difficult passing into the follicles—likely limiting topical and efficacy. Using patented technology to solubilize a novel 5% BPO lotion has been formulated for treating acne vulgaris in normal to oily skin. It is available as part of a 3-step system (together with a proprietary cleanser (clindamycin and a therapeutic moisturizer containing 20% glycerin and 1% dimethicone) and the potential to enhance follicular penetration and efficacy.

METHODS

Study design
- Investigator-blind, randomized study

Key inclusion criteria
- Mild to moderate facial acne:
  - 10-100 comedones
  - 17-40 papules + pustules + nodules
- Up to 3 head/neck lesions
- Normal to dry skin
- 40-48 years old
- Willing to refrain from using other non-acne related medications, restorers, hormones, fragrances, allergens, or use on the face (except to non-rosacea-congestive acne, rosacea, eyelid, and lipoedema were allowed)
- Willing to avoid excessive sun exposure and tanning booths

Key exclusion criteria
- Allergy to BPO, clindamycin, licochalcone a, salicylic acid, sunscreen, or any ingredient in the study products
- Facial scarring at the baseline visit
- Populational resistance to other skin diseases on the face other than acne which could interfere with study evaluation
- History of renal, hepatic, or amblyo-sensory colls.
-Cannot use any other products on the face
- Pregnancy or breastfeeding
- Participation in another investigational study in previous 30 days

Exclusion criteria:
- 1 month for medicated facial cleansers
- 2 weeks for topical alpha-hydroxy acids, anti-acne medications, topical retinoids, topical antibiotics, and systemic retinoids
- 3 months for isotretinoin and topical corticosteroids unless they were used at least 6 months ago

6criteria for systemic retinoids and local corticosteroids

Treatment regimen
- Patients were randomly assigned to receive once-daily treatment with the 3-step acne system (Figure 1) or with clindamycin and a proprietary cleanser (BPO/clindamycin) for 6 weeks. In the BPO/clindamycin group, patients washed their face twice daily with the proprietary cleanser containing 5% BPO to the entire face twice each morning and the proprietary therapeutic moisturizer in evening. The moisturizer could also be used on an as needed basis.
- In the BPO/clindamycin group, patients washed their face twice daily with a specific proprietary cleanser (Figure 2) and then applied the excellent 5% BPO 1% clindamycin prescription combination product to the entire face twice each morning.

Outcome measures
- Distance measure:
  - Corrected count
- Inflammatory lesion count (papules + pustules + nodules)
- Erythema, dryness, peeling, burning, stinging, itching, tingling, (Table 1)
- Patient rating of effectiveness of treatment (Table 2)
- Patient rating of acne improvement (Table 3)
- Patient satisfaction with acne improvement (Table 4)

Statistical analyses
- The following statistical tests were used to evaluate between-group differences: 2-sided chi-squared or Fisher’s exact test for gender and race, a 2-sided t-test for age, a 2-sided t-test or Wilcoxon rank-sum test or ANCOVA or Rank ANCOVA for percent reduction in lesion counts; a Wilcoxon rank-sum test for Hispanic skin type and patient ratings; and Rank ANCOVA or a Wilcoxon rank-sum test for tolerability assessments.
- A P value of <0.05 was considered statistically significant.

RESULTS

Patients
- 254 patients were enrolled:
  - 212 (83%) completed
- 1 withdraw due to non-compliance
- Patients had a mean age of 20 years and were predominantly:
  - Female (73%)
  - Caucasian (68% Caucasian, 18% Black, 5% Asian, 9% other)
  - Fitzpatrick skin I (55% I, 14% II, 18% III, 9% IV, 5% V).

Patent satisfaction
- Both regimens showed that the 3-step stabilized 5% BPO inter-benzoyl acne system was at least as effective as the enrolled BPO-clindamycin combination. Between baseline and week 4, no significant adverse events were reported with both regimens.
- In the BPO/clindamycin group, patients noted a 25% improvement in acne improvement from baseline to week 4 (P<0.05 by 2-sided t-test).
- In the 3-step acne system group, patients achieved a statistically greater improvement in acne improvement from baseline to week 4 (P<0.05 by 2-sided t-test) (Figure 5).

Patient tolerability
- Both regimens were generally well tolerated with mean levels of erythema, dryness, peeling, and burning/stinging (Table 1) rates less than at all time points (Figure 6).
- Although burning/stinging was reported with the acne system (likely due to the BPO being solubilized), it was typically minor and resolved within a few minutes after application. Also, it occurred primarily in the first 2 weeks of therapy. Nuisance with constant treatment, and more severe levels were noted to “have mild to moderate” it is better than with Ertacosen.

CONCLUSION

The 3-step acne system continued to be effective and well-tolerated. The acne system offered comparable efficacy and patient satisfaction compared to clindamycin and BPO combination products. The acne system may also provide a novel combination despite lack of an antibiotic.

DISCLOSURE

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