

A Novel Two-Step Topical Cosmeceutical Reduces the Appearance of Perioral Rhytides

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Introduction

Perioral rhytides are a troubling concern for many women as they age. This condition results from perioral muscle contraction and genetic predisposition, and is exacerbated by exposure to deleterious external factors such as cigarette smoke and ultraviolet light. Correction of perioral rhytides while maintaining a natural look can be challenging.

A **topical, cosmeceutical line plumper** has been developed for targeted use on fine and deep lines as an adjuvant or cosmetic alternative to injectable therapies. The **Step 1 Activator** is a light serum that contains a novel amino acid derivative, N-acetyl tyrosinamide, which has been shown to stimulate collagen production in aged skin cells *in vitro*¹; increase hyaluronic acid in skin and in cartilage cells *in vitro*; and stimulate pro-collagen and GAGs *in vivo* via histological assessment of human skin biopsies.² Step 1 also contains N-acetyl hydroxyproline and a low concentration of glycolic acid to aid in delivery. N-acetyl hydroxyproline has been shown to increase skin barrier function³ and is used as an amino acid source for collagen.

The **Step 2 Finishing Complex** is a lightly occlusive cream that contains complementary dermal matrix building ingredients, including triethyl citrate and N-acetyl glucosamine. N-acetyl glucosamine has been shown to increase hyaluronic acid in skin cells *in vitro*, and to increase skin thickness and improve the appearance of fine and coarse wrinkling *in vivo*.^{4,5} Triethyl citrate has been shown to increase collagen production in human dermal fibroblast cells *in vitro*.⁶

Results from a 16-week, double-blind, vehicle-controlled clinical study demonstrated statistically significant efficacy of the two-step line plumper versus its vehicle in reducing the appearance of glabellar lines, nasolabial folds, undereye wrinkles and crow's feet.⁷ **To investigate additional line-reducing benefits on a new target area, a follow-up, clinical-use study was conducted to assess the effects of this clinically-proven formulation on perioral rhytides.**

Study Methodology

| | |
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| Design | Dual center, single cohort, prospective use study |
| Population/Inclusion | Caucasian women (Fitzpatrick skin types I-III), aged 35–70 years, with visually apparent, mild to moderate, static perioral rhytides |
| Exclusion | Known allergies to skincare products; skin conditions or history of disease or use of medication that could interfere with evaluations; routine use of anti-aging topical products, including prescription retinoids within 3 months, hydroxyacids, retinol and other anti-aging cosmetics within 2 months; and/or cosmetic procedures within 6 months |
| Duration/Evaluation Time Points | 16–24 week duration depending on subject long-term availability with evaluations at weeks 0, 8, 16 and 24 |
| Clinical Evaluations | Clinical grading: <ul style="list-style-type: none"> Dermatologist grading of perioral rhytide severity using 0–3 scale (none, mild, moderate, severe) with 0.5 point increments, center 1 (n=10) Self-assessment: <ul style="list-style-type: none"> Questionnaires were completed by subjects: center 1 (n=10), center 2 (n=6) Clinical photography: <ul style="list-style-type: none"> Standardized digital photographs of faces were taken at each visit Center 1 (Canfield IntelliStudio), Center 2 (Canfield VISIA-CR) |
| Statistics | <ul style="list-style-type: none"> Clinical grading scores at each time point were compared to baseline scores using two-tailed, paired t-tests ($P < 0.05$) Self-assessment data were combined and tabulated |
| Safety | Adverse events were recorded and tabulated |

Test Products

| Product and Usage | Key Benefit Ingredients |
|---|--|
| Step 1 (NeoStrata® Skin Active Line Lift Activator) <ul style="list-style-type: none"> Applied directly to perioral rhytides Day + night use after cleansing | Proprietary blend of: <ul style="list-style-type: none"> N-acetyl tyrosinamide N-acetyl hydroxyproline Glycolic acid |
| Step 2 (NeoStrata® Skin Active Line Lift Finishing Complex) <ul style="list-style-type: none"> Applied over Activator/Step 1 to perioral rhytides Day + night use | Proprietary blend of: <ul style="list-style-type: none"> N-acetyl glucosamine Triethyl citrate Plus: palmitoyl oligopeptide and palmitoyl tetrapeptide-7 |
| All-over Facial Moisturizers Commercially available bland facial moisturizer SPF 15 <ul style="list-style-type: none"> Applied to entire face after application of Step 1 & Step 2 targeted treatments | No benefit ingredients |

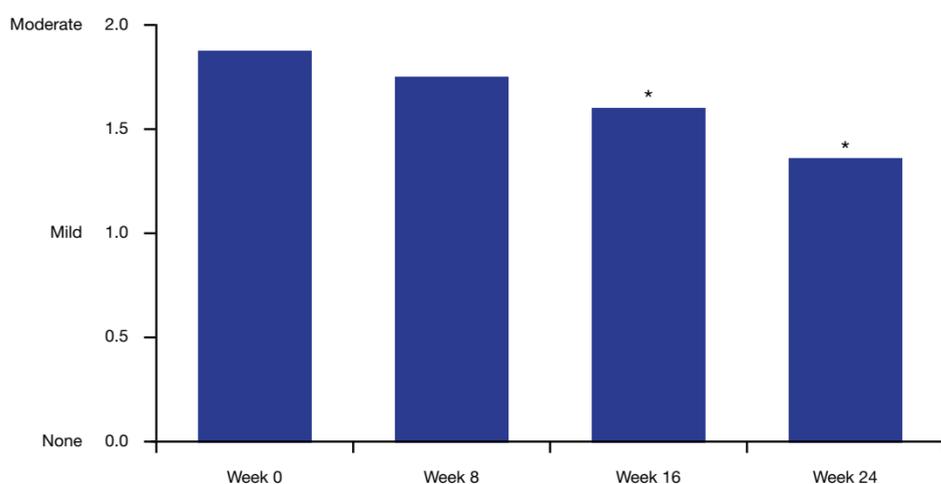
Results

16 subjects completed the study. The products were well tolerated and there were no adverse events reported at either center during the study.

The two-step, topical, cosmeceutical line plumper provided visible skin plumping effects to reduce the appearance of perioral rhytides.

> **Dermatologist grading** demonstrated a significant reduction in severity of perioral rhytides at weeks 16 and 24. (Figure 1)

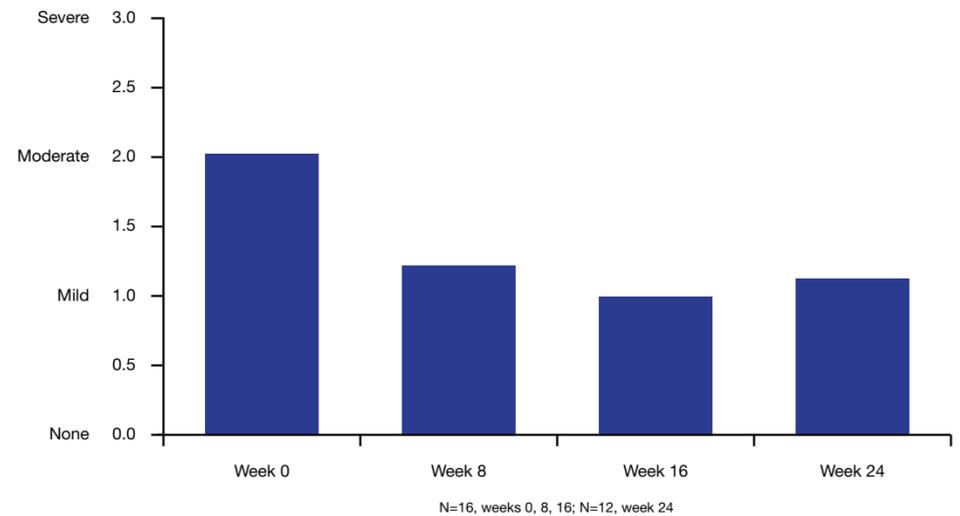
Figure 1. Dermatologist Grading: Improvement in Perioral Rhytides



> **Self-assessment** data supported clinical grading with perceived improvement to perioral lines.

- Mean self-assessed scores for severity of perioral rhytides improved from moderate to mild (Figure 2)
- 81% of participants agreed that their perioral lines were plumping/filling in (diminished) and that their skin looked and felt firmer after 16 weeks; 100% of participants agreed after 24 weeks, showing continued benefit with use
- 83% reported that the targeted perioral area looked younger
- 83% saw improvement in the overall appearance of their targeted perioral lines and wrinkles

Figure 2. Self-Assessment of Perioral Lines & Wrinkles



Clinical Photography

Clinical photography revealed visually apparent smoothing of perioral rhytides with a natural appearance. (Figures 3 and 4)

Figure 3. Plumping and softening of perioral rhytides



Figure 4. Improvement in perioral rhytides with smoother, brighter skin



Conclusions

Dermatologist grading revealed that the two-step, topical cosmeceutical line plumper significantly reduced the appearance of perioral rhytides at 16 and 24 weeks. Clinical photography confirmed a natural-looking improvement to the targeted wrinkle area, which was supported by self-assessment. This data supplements previous clinical study results which showed significant reductions in the appearance of other target wrinkles including, glabellar lines, nasolabial folds, crow's feet and periocular lines versus a vehicle control.⁷ This new, cosmeceutical line treatment diminished the appearance of perioral rhytides and can be used to provide cosmetic improvement for this common aging concern.

References

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