A Multifaceted Calming Serum Significantly Improves **Facial Redness and Signs of Aging in Combination** with a PHA/Bionic Acid Skincare Regimen

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Introduction

Self-perceived sensitive skin is prevalent in the consumer market; those with visible erythema, heightened sensory awareness or rosacea-prone skin desire beneficial skincare beyond camouflaging cosmetics to improve their appearance.

An elegant serum was formulated with a tripeptide, algae extract and Canadian Willowherb extract to help soothe neurosensory cues and redness, and to calm irritation. The serum also contains a 6% polyhydroxy acid (PHA)/Bionic acid blend; these ingredients have been shown to help reinforce the skin matrix and increase barrier function.¹⁻⁴

This poster presents a summary of a 12-week clinical study evaluating redness-reduction, antiaging cosmetic effects and tolerability of the Serum when used in conjunction with a high-strength PHA/Bionic acid regimen.

Clinical Photography

Figure 1. Continued Improvement in Redness on Cheeks, Nose and Forehead Through Week 12







Week 6



Week 2

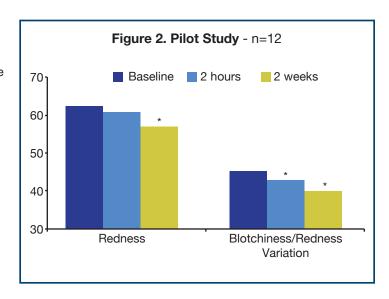


Week 12

Image analysis applied to highlight redness parameter

Pilot Study: Redness-Reduction Benefits of Calming Serum Over 2 Hours and 2 Weeks

In a pilot study, 12 subjects used the Serum to determine if short-term benefits could be observed. Subjects applied the serum once and after 2 hours image analysis was performed using the Clarity Pro imaging system to assess redness and blotchiness/redness variation. Subjects continued to use the Serum twice daily for 2 weeks and image analysis was repeated. The Serum provided significant redness-reduction at both 2 hours and 2 weeks (*p≤0.02) (Figure 2). In addition, subject self-assessment demonstrated 92% of subjects rated the skin less red after 2 weeks. Benefits of the Serum in combination with a PHA/Bionic acid skincare regimen were assessed after 2, 6 and 12 weeks as detailed below.



Study Methodology

<u>Design</u> – A 12 week, single center, prospective study with direct comparison to baseline condition

Population

Key Inclusion:

- Women, ages 35-65 years
- Self-reported flusher/blushers
- Clinically graded mild to moderate facial redness (1.5-3 on 5 point scale) and photoaging (either pigmentation: 1-3 on 5 point scale or fine lines or wrinkles: 3-7 on 10 cm analog scale)

Key Exclusion:

- Current use of OTC, Rx or other treatment for rosacea
- > Routine use of antiaging topical products, including:
 - Rx retinoids within 3 months;
 - hydroxyacids, retinol and other antiaging cosmetics within 2 months;
 - cosmetic procedures (e.g. peels, laser, light treatments, microdermabrasion) within 6 months

Evaluation Tools - Weeks 0, 2, 6 and 12

Clinical Measures – Visual grading by an expert grader:

- Redness and pigmentation (0-4 scale)
- Crow's feet lines, global fine lines/wrinkles, texture, laxity and brightness (10 cm analog scale)
- Irritation/tolerability including dryness (0-4 scale) and stinging, itching, burning (0-3 scale)

Subjective Measures – Self-Assessment questionnaires were completed by subjects

Digital Photography with Image Analysis of Redness and Brightness (Clarity 2D Research System Ti camera system; BrighTex Bio-Photonics (BTBP))

Safety - Adverse events were recorded and tabulated

Statistics - Clinical improvements were compared to baseline at each visit using a paired t-test (p≤0.05)

Test Products

The regimen included twice daily use of a Cleanser followed by the Serum with either a Day Cream SPF 23 or a Night Cream over top.

Serum (NeoStrata® Redness Neutralizing Serum)

- 6% PHA/Bionic Acid Blend to help reinforce the skin matrix and increase barrier function
- Palmitoyl TriPeptide-8, Algae Polysaccharide Complex, and Canadian Willowherb extract to help soothe neurosensory cues and redness, and to calm signs of irritation
- Includes Botanicals, Bisabolol, and White Tea Extract

<u>Regimen</u>

- 4% PHA Cleanser (NeoStrata® Facial Cleanser)
- > 10% PHA/Bionic Acid Day Cream SPF 23 (NeoStrata® Daytime Protection Cream SPF 23)
- 10% PHA/Bionic Acid Night Cream (NeoStrata® Ultra Moisturizing Face Cream)

Results

Forty-two women completed the study.

Clinical Grading

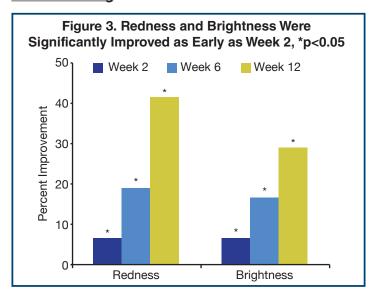


Table 1. Photoaging Parameters Showed Significant Improvement From Baseline, ✓ p<0.05

Parameter	Week 2	Week 6	Week 12
Crow's Feet		√	√
Global Fine Lines/Wrinkles		√	√
Texture/Smoothness	✓	✓	✓
Laxity	√	√	√
Pigmentation	✓	✓	✓

Image Analysis for Redness and Brightness

- > Redness intensity significantly improved at Weeks 6 and 12, p<0.002
- ➤ Brightness (L*) significantly improved at Weeks 2, 6 and 12, p<0.001

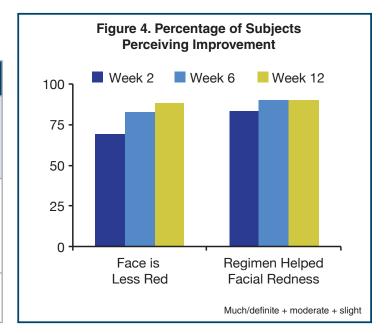
Self-Assessment

Self-assessment supports clinical grading and image analysis demonstrating reduced redness and flushing/blushing

Table 2. More Subjects Rated Their Condition as LESS Than MILD[†] With Continued Use of the Regimen, *p<0.05

Percentage of Subjects Rating the:	Week 0	Week 6	Week 12
Amount of redness as LESS than MILD [†]	41%	71%*	83%*
Degree of flushing/blushing as LESS than MILD [†]	38%	81%*	86%*

[†]Less than mild is percentage of subjects rating 0 or 0.5 (less than mild); 0-3 scale with half point increments; descriptors at whole points where 0=none, 1=mild, 2=moderate, 3=severe



Tolerability

- > The Serum and product regimen were well tolerated in this sensitive flusher/blusher population
 - Mean dryness and itching were less than mild to start and significant improvements were seen at all time points (2, 6, 12 weeks), p<0.05
 - There were no reports of stinging or burning at any post-baseline time point
 - One Adverse Event was reported: a mild outbreak of papules on the cheek. There was no interruption or discontinuation of the test products.

Clinical Photography

Figure 5. Obvious Decrease in Redness After 12 Weeks Use of the Serum and Regimen







Week 6 Week 12

Figure 6. Overall Reduction in Redness After 12 Weeks Use of the Serum and Regimen





Baseline

Week 12

Conclusions

- A significant reduction in Redness and Flushing/Blushing was demonstrated through clinical grading, image analysis, and self-assessment using the Calming Serum and Regimen of PHA/Bionic Acid products
- > Photoaging parameters significantly improved with the Regimen
- > The Regimen was well tolerated and gentle, with improvements to dryness and itching and no stinging or burning
- ➤ The multifaceted Calming Serum and PHA/Bionic Acid Regimen provide substantial anti-aging and redness reducing benefits, both clinically and consumer perceivable, thereby improving the overall appearance of skin for those with visible erythema or rosacea-prone skin

References

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- 3. Berardesca E, Distante F, Vignoli GP, Oresajo J, Green B. Alpha hydroxyacids modulate stratum corneum barrier function. *Br J Dermatol* 1997; 137: 934-938.
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