

THE EFFECT OF AN ANTI-INFLAMMATORY BOTANICAL CLEANSER/ NIGHT MASK COMBINATION ON FACIAL REDNESS REDUCTION

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SYNOPSIS

Facial redness is a common, difficult to control cosmetic problem representing various phases of rosacea. Using anti-inflammatory/antioxidant botanicals in moisturizer formulations is a possible approach to minimizing the erythema. This research utilized a common facial cleanser, but only applied the botanically based moisturizer to one half face to properly assess efficacy. 30 female subjects Fitzpatrick skin types I-IV 30-55 years of age with mild to moderate chronic facial redness, defined as a redness score of 3-6 on a 10-point scale, were enrolled. By the end of week 4, statistically significant improvement was seen on the cleanser/mask treated side in scaling (p<0.001), flaking (p<0.001), tactile smoothness (p<0.001), textural smoothness (p<0.001), firmness (p<0.001), radiance (p<0.001), luminosity (p<0.001), and overall appearance (p<0.001). Thus, cosmetic moisturizers may be useful in reducing facial redness.

OBJECTIVE

The objective of this research was to examine the moisturizing and redness reducing effect of an anti-inflammatory botanical calm and repair night mask plus sulfate free foaming oil cleanser in subjects with mild to moderate facial redness.

METHODS

30 Female subjects Fitzpatrick skin types I-IV and 30-55 years of age with mild to moderate chronic facial redness, defined as a redness score of 3-6 on a 10 point scale, were enrolled in this single-site split face study. Subjects applied the cleanser to the entire face (Skinfix Foaming Oil Cleanser) and were randomized to apply a dime-sized amount of the study mask (Skinfix Calm & Repair Sleeping Mask) only to one side of the face at bedtime, leaving the untreated side as a control. Every attempt was made to enroll subjects with symmetrical facial redness to insure the validity of the results. The blinded dermatologist investigator visually assessed by the subjects for the following efficacy criteria on a 10-point scale (0=none to 9=extremely severe): erythema, capillaries, blotchiness, scaling, flaking, tactile smoothness, textural smoothness, firmness, radiance, luminosity, and overall appearance. Each side of the face was separately assessed to allow each subject to act as their own control. The investigator also assessed product tolerability. Photography, corneometry, and D-squames were performed. Subjects were evaluated at baseline, immediately post-application, 1 day, 1week, and 4 weeks.

RESULTS

Investigator Assessments

At day 1, there was statistically significant improvement in tactile smoothness (p=0.002) and textural smoothness (p<0.001) in the botanical anti-inflammatory cleanser/mask treated facial side as compared to the cleanser only side (Figure 1). The cleanser alone control showed improvement after 1 week of use in scaling (P=0.027), flaking (p=0.040), tactile smoothness (p=0.012) and textural smoothness (P= 0.027)(Figure 2). The improvement continued into week 4. Cleanser mildness was due to the sulfate-free formulation, which was created by excluding sodium lauryl sulfate and sodium laureth sulfate.

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CORNEOMETRY

The corneometry measured the amount of water present in the skin as change from baseline. Immediately after application, the skin hydration on the randomized mask applied facial side was statistically significantly superior (p<0.001) to the nontreated side of the face by 78% at day 1. This superior hydration due to the moisturizer and cleanser continued into week 1 (p=0.002) and week 4 (p=0.004) over the cleanser only side of the face.

D-SQUAMES

The D-Squame was a piece of tape placed on the upper cheek on both sides of the face for exfoliation analysis. Both sides of the face showed a reduction in skin scale of 9% at week 1 and the cleanser/mask side showed 11% reduction at week 4 while the cleanser side only showed a reduction in skin scale of 12%. Thus, both the cleanser and the mask were effective in reducing retained skin scale.

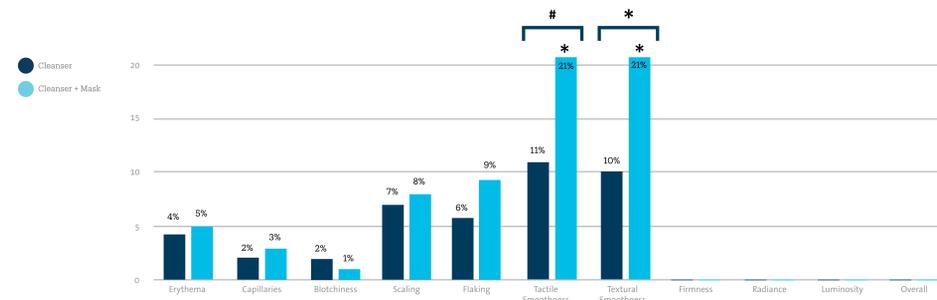
CONCLUSION

The anti-inflammatory botanically based night time mask and cleanser provided excellent moisturization, minimized barrier damage and facial redness. This combination demonstrated no tolerability or safety issues in a challenging population of females with mild to moderate facial erythema.

DAY 1

INVESTIGATOR EFFICACY ASSESSMENT

Mean change from baseline within and between the regimen and cleanser only groups.

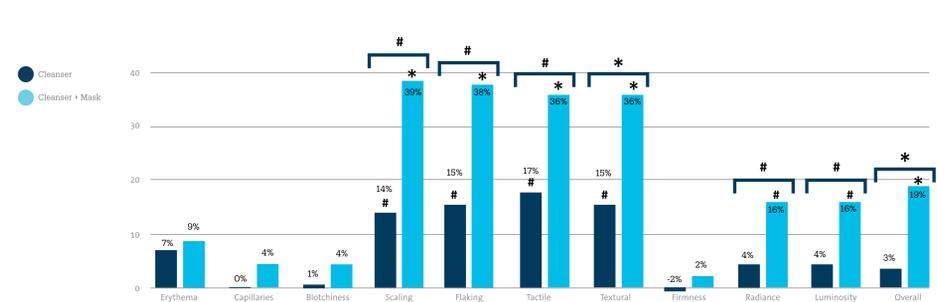


Skin improvement occurred earlier with the combined anti-inflammatory night mask and cleanser

WEEK 1

INVESTIGATOR EFFICACY ASSESSMENT

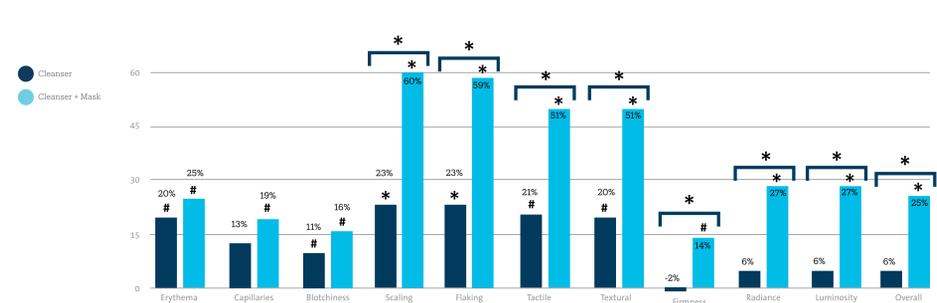
Mean change from baseline within and between the regimen and cleanser only groups.



WEEK 4

INVESTIGATOR EFFICACY ASSESSMENT

Mean change from baseline within and between the regimen and cleanser only groups.



The addition of the anti-inflammatory botanical night mask to the cleanser resulted in additive improvement.



TREATED & UNTREATED

Representative photograph taken with cross-polarized light demonstrating the redness reduction with the cleanser + mask combination