

USE OF A LIQUID CREAM IMPROVES SENSITIVE ROSACEA-PRONE SKIN

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ABSTRACT

A uniquely formulated liquid cream was evaluated to determine the potential for alleviating the signs and symptoms of sensitive or reactive skin including rosacea-prone skin. A screening questionnaire was developed to identify these individuals with sensitive skin. Twenty-two subjects ages 28 to 60 identified by this questionnaire as having sensitive facial skin were recruited and evaluated by a dermatologist for erythema, dryness, and inflammatory lesions. In addition to erythematotelangiectatic rosacea, some of the subjects had mild to moderate papulopustular rosacea. For four weeks they applied the liquid cream twice daily to their faces. A self-assessment questionnaire was also obtained and the subjects were reevaluated clinically at four weeks. The test formulation was well tolerated by all the subjects without adverse reaction. By self-assessment statistically significant improvement was noted in skin reddening, flushing, visible blood vessels, skin texture, and overall skin condition. Statistically significant improvement in objectively graded erythema, dryness, inflammatory lesions and globally was seen at four weeks.

BACKGROUND

Consumer research has consistently found that 50% of women consider themselves to have sensitive skin (1). Currently available methods of objective assessment do not correlate well with patient self-assessment of sensitive skin (2). It is reasonable to consider sensitive skin as a variation of normal skin that is hyperresponsive to some external stimulus. Reduced stratum corneum barrier function seems to correlate best with sensitive skin types (3). A precise clinical definition of sensitive skin has not been established (4).

Dermatologists have over the years considered the sensitive skin phenotype to include a higher percentage of fair complected individuals, who sunburn readily with an atopic background. Atopics have reported a higher incidence of sensitive facial skin (1). Barrier function may be diminished in these individuals. However, regardless of ethnicity, a recent study demonstrated that individuals with European, Asian, African-American or Hispanic backgrounds all consistently identified themselves at a rate of 52% (5).

One clinical subgroup of individuals with sensitive skin manifests a tendency to flush or blush readily as a result of environmental factors (6). The CERIES Institute in Paris (Chanel) has developed a classification of sensitive skin based on reddening induced by environmental factors more consistent with rosacea-prone skin. The report of the National Rosacea Society Expert Committee on the Classification and Staging of Rosacea (7) classifies four subtypes of rosacea. Subtype 1, erythematotelangiectatic, is characterized by flushing and persistent facial erythema. Telangiectasias are common. This subtype is less responsive to topical treatment than Subtype 2: papulopustular. Subtypes 3, phymatous with thickened features and subtype 4, ocular, would not be subject to the proposed study.

The primary signs of rosacea include flushing (transient erythema), nontransient erythema, papules and pustules and telangiectasia. These signs, excluding flushing, are suitable for objective grading and show improvement with topical therapies. Flushing can be assessed by subject self-assessment. This latter feature is generally refractive to topical therapy. Rosacea-prone individuals also report susceptibility to subjective skin burning, itching and stinging to a variety of environmental factors including some topical agents. All of the above signs and symptoms may be triggered by the environment including diet and would currently be considered by the dermatologic community as part of the sensitive skin phenotype. A screening questionnaire was developed to identify individuals with these skin types.

METHODS

- Twenty two subjects (19 female, 3 male) ages 28 to 60 were selected with sensitive skin and/or rosacea determined by questionnaire and clinical examination. Rosacea subjects were subtype 1 and 2 (National Rosacea Society Expert Committee) of mild to moderate severity. All subjects were examined by a board-certified dermatologist and graded bilaterally as follows for:
 - Erythema
 - Inflammatory lesions (papules and pustules)
 - Dryness
 - Global Inflammatory lesions were individually counted.
- Applications with the test product were made twice daily. Subjects were allowed to continue to use their existing cleanser, if determined appropriate by the physician, and their color cosmetics. The study product acted as moisturizer and daily sunscreen.
- All subjects were graded as described above at baseline and four weeks. Subjects were allowed to sit quietly after coming into the clinic and removing makeup if necessary, for at least ten minutes prior to being evaluated. Subjects completed a self-assessment questionnaire by phone at the two week interval and at the study site at the end of the study.

TEST PRODUCT

The test product was formulated as a liquid cream to provide adequate emolliency, yet remain cosmetically acceptable to individuals with the sensitive/rosacea-prone skin type. The following ingredients were included:

INGREDIENT(S)	FUNCTION
3-Hydroxybenzoic Acid	a beta-hydroxy alternative to salicylic acid
Zinc Oxide/Titanium Dioxide	inorganic particulate sunscreen for full spectrum uv protection
Lipids	barrier function restoration
Dimethicone	skin protectant
Bisabolol	active principal in chamomile for anti-irritant properties
Botanical Extracts	additional anti-irritant effects
Pigments	green color corrector for underlying skin redness

TABLE 1
SUMMARY SUBJECT ATTRIBUTES (n=22)

ATTRIBUTES	# YES	% YES	# NO	% NO	# UNSURE	% UNSURE
Sensitive Skin	21	95	0	0	1	5
Very Sensitive	12	55	8	36	2	9
Easily Irritated	18	82	3	14	1	5
Easily Reddening	16	73	1	5	5	23
Visible/Prominent Blood Vessels	8	36	10	45	4	18
Acne Breakouts	6	27	15	68	1	5
Environment Aggravates	19	86	1	5	2	9
Diet Aggravates	8	36	9	41	5	23
Emotional Stress Aggravates	14	64	5	23	3	14
Stinging	18	82	4	18	0	0

SKIN TYPE	# PANELISTS	% PANELISTS
Oily	0	0
Normal	5	23
Dry	8	36
Combo	9	41

TABLE 3
Rosacea Study Dermatologist Assessment (n=22)
SENSITIVE SKIN EVALUATIONS
SIGNIFICANCE RESULTS

ATTRIBUTES	WEEK 0	WEEK 4	STATISTICAL SIGNIFICANCE
	MEAN		
Erythema	3.18	1.82	S
Inflammatory Lesions	5.05	1.73	S
Dryness	1.68	0.77	S
Global	3.00	1.71	S

NOTE: S = Significant Difference at the 95% Confidence Level versus baseline NS = Not Significant
7 Point Rating Scale: 0 = Clear; 1 = Minimal; 2 = Mild; 3 = Mild to Moderate; 4 = Moderate; 5 = Moderate to Severe; 6 = Severe

TABLE 2
CONSUMER PERCEPTION (n=22)
(Week 4 of 4-Week Study)

ATTRIBUTES	MEAN	TOP 2 BOX AGREE COMPLETELY AGREE SOMEWHAT
Reduces inflamed bumps	3.7	50%
Reduces skin redness (immediate skin reddening)	4.5	91%
Reduces flushing	4.0	77%
Reduces visible blood vessels	4.0	68%
Reduces susceptibility to burning	3.6	41%
Reduces susceptibility to stinging	3.9	59%
Reduces susceptibility to itching	3.8	55%
Improves skin dryness	4.4	86%
Improves overall skin condition	4.4	91%
Reduces susceptibility to environmental or dietary factors that trigger Rosacea	4.4	27%
Skin feels smoother	4.4	86%
Improves skin's texture	4.4	91%
Helps even skin color and tone	4.2	82%

RESULTS

The demographics of the test panel based on the screening questionnaire are shown in Table 1. In addition, all subjects could be classified as being rosacea prone or having some degree of intrinsic facial erythema based on their initial evaluation. Responses to self-assessment questionnaire at week 4 are shown in Table 2. No subjects reported any adverse reactions with the test article nor were any observed during the course of the study or at the final evaluation. Dermatologist objective evaluation results are shown in Table 3. Statistically significant improvement was seen in all graded parameters including erythema, inflammatory lesions, dryness scores and global evaluation.

DISCUSSION

By any measure, this panel can be considered to have sensitive skin by self-assessment with greater than 95% considering themselves to have sensitive skin and 55% very sensitive skin. Most considered themselves to be easily irritated with reddening and subject to symptoms of stinging, burning and itching.

Dryness scores at baseline in this study were relatively low as a function of the time of year the study was done (late summer to fall in North Carolina, USA) and the use of some moisturizing products prior to the study. Vehicles alone have been shown to improve some parameters of rosacea independent of active ingredients. Improvements in severity scores in this study are striking in that improvements were noted in subjects who already had adequate skin hydration at baseline with low dryness scores.

Improvement in skin condition was noted by the subjects with objective evaluation showing statistically significant improvement at the 4 week evaluation in all parameters. Erythema in rosacea-prone individuals tends to vary widely in relatively short time periods. Subjects were given sufficient time prior to their evaluations to minimize more transient erythema. The overall lower percentage agreement with "reduces inflamed bumps" is a function of fewer subjects at baseline evaluation demonstrating inflamed papules as part of their presentation. Objective effect with a decrease in inflammatory lesions was also significant.

Low percentage agreement with the attribute that the test article reduces susceptibility to environmental or dietary factors triggering rosacea may have been a function of subjects having difficulty assessing this parameter. All other consumer perception parameter responses reported greater than 50% agreement.

CONCLUSION

Twenty-two individuals who could be readily classified as having sensitive skin or low-grade rosacea were given the test article to apply to their face twice a day for four weeks as their sole skin treatment. By self-assessment the vast majority saw an improvement in their skin condition. Dermatologist evaluations revealed a statistically significant improvement in erythema, inflammatory lesions and global scores. Under the conditions of this study, the test product could be considered both safe and effective for reducing the signs and symptoms of sensitive skin with and without active mild to moderate rosacea.

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The authors would like to thank Gale Reinhart, Beverly Reisinger and Kristin Latner for their assistance in the preparation of the test product.
This study was supported by a grant to Almay from the Revlon Research Center.