

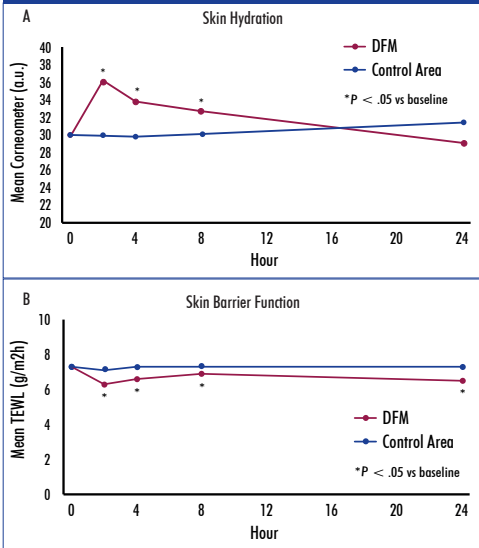
TOLERABILITY AND EFFICACY OF A MOISTURIZING BROAD SPECTRUM SUNSCREEN FORMULATED FOR REDNESS-PRONE SKIN

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INTRODUCTION

Rosacea affects over 16 million Americans and is characterized by highly reactive skin with flares commonly induced by normally benign external stimuli. While cleansing and moisturizing is paramount to helping to maintain healthy skin, many skincare formulations may be formulated with ingredients that are irritating to rosacea skin. Common irritants and triggers include organic UV filters, fragrances, and harsh surfactants among others. A broad spectrum SPF 20 facial moisturizer (Cetaphil Daily Facial Moisturizer with Broad Spectrum SPF 20 [DFM]) was developed specifically for patients with redness-prone skin. This formula contains inorganic UV filters to protect against irritation and sun damage and a neutral tint to improve the appearance of facial erythema. Additionally it is also formulated with allantoin, caffeine, licorice root extract, and vitamin E to help calm and soothe rosacea-prone skin. This poster presents the results of two clinical studies that assessed the performance and tolerability of DFM.

Figure 1. Investigator Assessments



SUBJECTS and METHODS

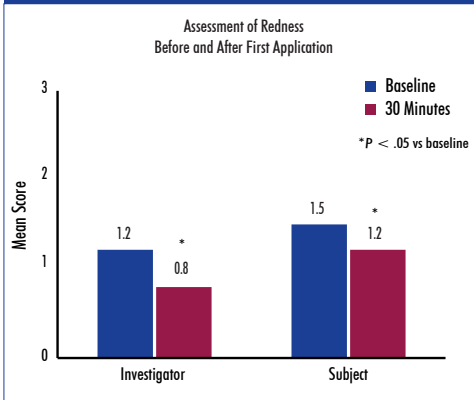
Study 1: Hydration and Skin Barrier Function

- Men and women with dry volar forearms
- Inner forearms randomized to treated and control
- 40 mg of product applied to 20 cm²
 - Corneometer and transepidermal water loss (TEWL) assessed at baseline and 2, 4, 8, and 24 hours

Study 2: In Use Efficacy and Tolerability

- Men or women with rosacea and mild to moderate non-transient erythema
- Product applied QD in the morning for 3 weeks
- Assessments made on day 1 before application, day 1 30 minutes after first use and days 3, 8, and 22 before product application
 - Objective (chromameter) and subjective (investigator and subject) assessment of redness
 - Investigator and subject tolerability assessments
 - Redness and tolerability assessments made on a 5 point scale of 0 (none), 0.5 (very slight), 1 (slight), 2 (moderate) and 3 (strong)
 - Subject satisfaction

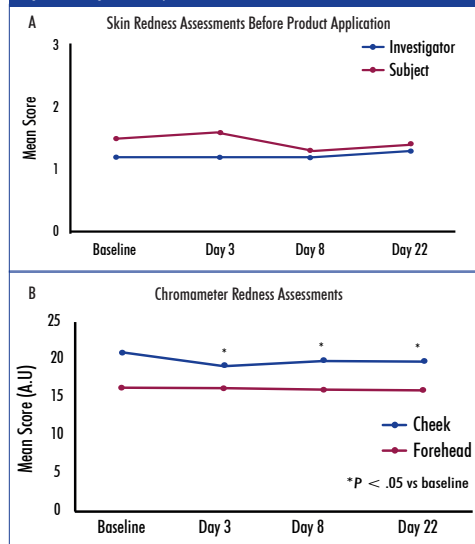
Figure 2. Investigator and Subject Assessed Facial Redness (n=30)



RESULTS

Skin hydration and skin barrier function significantly improved for 8 and 24 hours, respectively (Figure 1). For the in use study, 33 women enrolled with 30 completing the study (the 3 dropouts were unrelated to the study product); 91% of the subjects also presented with sensitive skin. The mean age was 53.7 years. Investigator and subject assessed skin redness significantly improved immediately after application (Figure 2). There was no significant worsening of erythema during the study as assessed after product application (Figure 3). Skin dryness and feelings of tightness also significantly improved compared to baseline (Figure 4). The product was well tolerated with mean scores for all parameters less than mild (data not shown). Subjects demonstrated high satisfaction with the product (Figure 5). One mild, possibly related adverse event (AE) of exfoliative and dry small area on the neck was reported. Three additional unrelated AEs were also reported: extraction of 3 teeth with anesthesia, stitches removed, and heartburn.

Figure 3. Investigator and Subject Assessments



SUMMARY

DFM significantly improves skin hydration and skin barrier function and is an ideal daily broad spectrum facial moisturizer for patients with rosacea and sensitive skin

Figure 4. Subject Assessment of Dryness and Tightness (n=30)

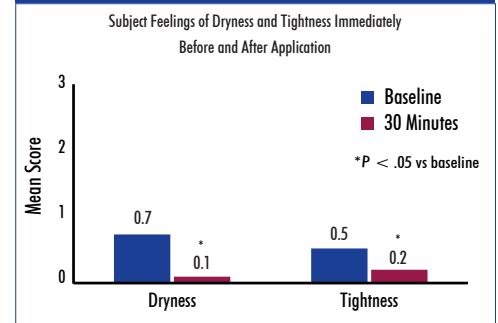


Figure 5. Subject Satisfaction (n=30)

