

New Technology Provides Cosmetically Elegant Photoprotection



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The primary preventable cause of photoaging is exposure to UVA radiation. This wavelength emitted by the sun is present year round in all latitudes. Currently, the majority of sun-protective products provide excellent UVB protection with minimal UVA protection. Although UVB protection is important in order to prevent sun damage to the skin from occurring, UVA protection is equally important. New developments in raw material science have led to the manufacture of novel ingredients able to provide unprecedented photoprotection in the UVA spectrum.

One of the most significant developments in cutaneous UVA protection was the discovery of ecamsule (Figure 1), also known as Mexoryl SX. Mexoryl SX, which has the International Nomenclature of Cosmetic Ingredients name of terephthalylidene dicamphor sulfonic acid, is water soluble. It is a benzylidene camphor derivative from the family of photoprotectants that is known for excellent photostability. Mexoryl SX was approved by the US Food and Drug Administration for use as a sunscreen; however, it has not been added to the sunscreen monograph.

Ecamsule is a unique photostable UVA sunscreen ingredient. When a photon of UVA radiation strikes ecamsule, it undergoes reversible photoisomerization followed by photoexcitation. The absorbed energy is radiated from the skin as heat. This transformation of UVA radiation into heat prevents photoaging. However, the ability of ecamsule to protect the skin against UVA radiation cannot be listed on the packaging in the

United States, as there is no official rating system for UVA photoprotection yet.

Ecamsule absorbs UVA radiation in the range of 320 to 360 nm, but its peak absorbance occurs at 345 nm. It is typically combined with other organic sunscreen ingredients, such as avobenzone and octocrylene. Avobenzone, which is a photounstable photoprotectant, becomes photostable when combined with octocrylene. These ingredients yield a photostable broad-spectrum sunscreen combination. However, the active sunscreen agents are only part of the formulation. Also important in sunscreen is the construction of the vehicle to deliver the photoprotectants in an aesthetically pleasing manner, enticing patients to wear the product. Sunscreens fail to be effective if they remain in the bottle.

In order to evaluate the efficacy and tolerability of a moisturizing sunscreen containing ecamsule in combination with avobenzone and octocrylene, a research study was executed with a new FDA-approved daily moisturizer with a sun protection factor (SPF) of 15.

Method

The 12-week, single-center study enrolled 25 healthy, nonpregnant female subjects ranging in age from 35 to 65 years who displayed mild to moderate fine lines, wrinkles, and hyperpigmentation. All subjects signed an institutional review board–approved informed consent form and were asked to use a provided cleanser twice

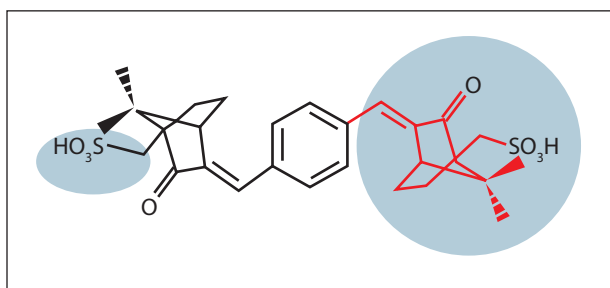


Figure 1. The chemical structure of ecamsule.

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daily and the SPF 15 daily moisturizer in the morning. Assessments were performed at baseline and weeks 2, 4, 8, and 12. Measurements included investigator ordinal grading of fine lines, wrinkles, radiance, skin roughness, skin tone, hyperpigmentation, and global assessment at each visit. The ordinal scale was defined as follows: 0=none, 0.5=very minimal, 1=minimal, 1.5=very mild, 2=mild, 2.5=moderate, 3=moderately severe, 3.5=severe, and 4=extremely severe. The investigator also performed an objective assessment of erythema, scaling, and acne in addition to asking subjects for their perception of product-induced itching and stinging. The previously described ordinal rating scale was used. Subject self-assessments were also obtained at each visit using the ordinal scale in terms of lines, wrinkles, dryness, redness, color, acne, peeling, itching, and stinging. Compliance was determined from diaries completed by the subjects.

The study also incorporated noninvasive assessment techniques at baseline and weeks 2, 4, 8, and 12. Corneometry, the measurement of the water contained in the skin through electrical impedance, was evaluated along with chromameter measurements in order to evaluate skin redness and melanin content. Both readings were taken from the medial cheeks in an area representative of the entire face. Digital photographs were obtained for documentation and showed the face at full-frontal view, 45° to the right, and 45° to the left.

Results

All 25 female subjects who enrolled successfully completed the study. No adverse experiences were encountered during the study, providing an excellent tolerability profile. All of the ordinal data were analyzed utilizing a 2-tailed, unpaired Mann-Whitney *T* test with significance defined at the level of $P \leq .05$.

The investigator noted improvement in a variety of different areas both early and late in the study (Figures 2 and 3). At the end of week 2, the investigator noted statistically significant improvement in radiance ($P = .029$), a visual assessment of the reflectivity of the skin, and

roughness ($P = .001$). Continued improvement was noted at week 4, with statistically significant improvement in radiance ($P < .001$), roughness ($P < .001$), and overall global assessment ($P < .001$). Week 8 revealed continued improvement in skin appearance with statistical significance in skin radiance ($P < .001$), roughness ($P < .001$), scaling ($P = .027$), and tone ($P = .004$) and overall global

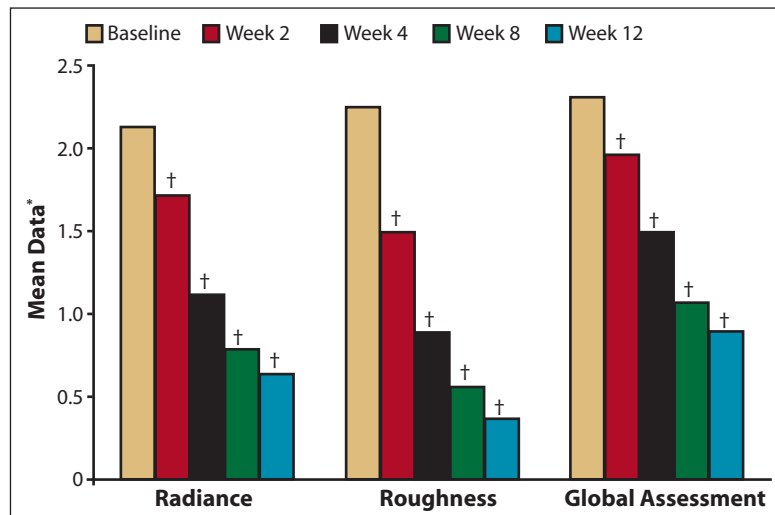


Figure 2. Grading results showing the improvement of skin radiance and roughness and global assessment in patients using a moisturizing sunscreen containing ecamsule in combination with avobenzone and octocrylene from baseline to week 12. Asterisk indicates clinical significance ($P \leq .05$); dagger, changes based on a scale of 0 to 4, where 0=none, 0.5=very minimal, 1=minimal, 1.5=very mild, 2=mild, 2.5=moderate, 3=moderately severe, 3.5=severe, and 4=extremely severe.

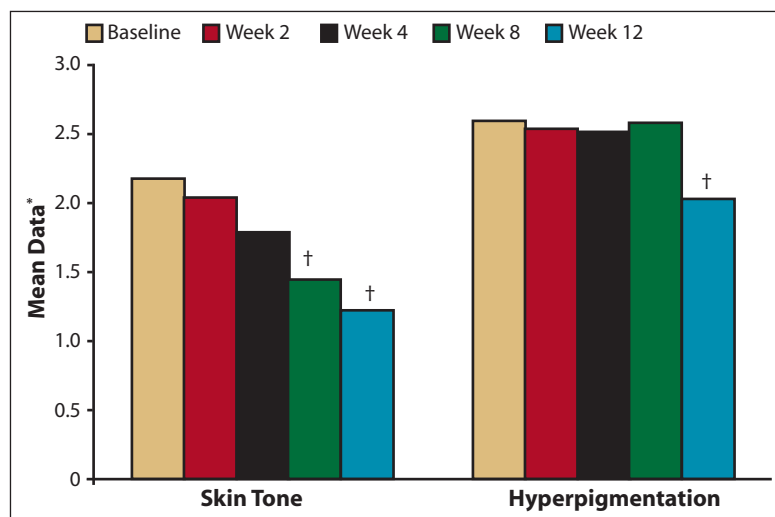


Figure 3. Grading results showing the improvement of skin tone and hyperpigmentation in patients using a moisturizing sunscreen containing ecamsule in combination with avobenzone and octocrylene from baseline to week 12. Asterisk indicates clinical significance ($P \leq .05$); dagger, changes based on a scale of 0 to 4, where 0=none, 0.5=very minimal, 1=minimal, 1.5=very mild, 2=mild, 2.5=moderate, 3=moderately severe, 3.5=severe, and 4=extremely severe.

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assessment ($P < .001$). Finally, by week 12, the investigator noted improvement in radiance ($P < .001$), roughness ($P < .001$), scaling ($P = .027$), tone ($P < .001$), pigment ($P = .026$), and overall global assessment ($P < .001$). The investigator data demonstrated that the SPF 15 daily moisturizer produced immediate improvement in the appearance of the skin that gradually continued.

The investigator data were collaborated by the subject data. The subjects noted a statistically significant lightening of skin color at weeks 4 ($P = .015$) and 8 ($P = .020$) as a result of applying the SPF 15 daily moisturizer. They also reported a statistically significant ($P = .015$) improvement in skin dryness at week 4. No increase in acne, peeling, itching, or stinging, was reported by the subjects during the use of the product, yielding an excellent safety profile.

Noninvasive assessments also confirmed the investigator and subject impressions of excellent skin moisturization with the study product. Corneometry measurements increased, indicating enhanced water content in the skin, following once-daily use of the SPF 15 daily moisturizer. A statistically significant improvement in skin hydration was measured at weeks 2 ($P = .002$), 4 ($P = .028$), and 12 ($P = .003$). These data reflect the ability of the SPF 15 daily moisturizer to produce a rapid and continued increase in skin hydration.

Chromameter measurements for melanin showed a trend toward skin lightening over the 12-week study with the average melanin reading of 34.36 at baseline decreasing to 33.24 at week 12; however, these data were not statistically significant. This may have been due to the small sample size and the 12-week duration. However, the study was conducted in High Point, North Carolina, from January to May 2007, and increased melanin might have been expected because of the seasonal change from winter to spring in a southern latitude. The slight pigment lightening that occurred may have been due to

the use of the SPF 15 daily moisturizer. Similarly, there was also a gradual trend toward decreased facial erythema from 16.23 at baseline to 13.99 at week 12. This is noteworthy because it indicated the absence of product-induced inflammation.

Comment

One of the biggest challenges dermatologists face is convincing patients to wear sunscreen on a daily basis. There is no doubt that the best treatment for facial photoaging is the prevention of further photodamage and the creation of a UV-free environment for photorepair. The only ingredients that can provide this type of protection for the face are sunscreens. Older sunscreen formulations contained greasy organic photoprotectants that left a sticky, heavy film on the face. Their UVA-protective abilities were limited along with their photostability. New sunscreen ingredients, such as ecamsule in combination with photostable avobenzone and octocrylene, provide excellent long-lasting UVA and UVB photoprotection that is cosmetically elegant. This study demonstrated excellent tolerability of these sunscreen ingredients in a daily moisturizer containing SPF 15 when applied to the face and produced investigator-observed improvement in global facial appearance after 12 weeks of use as compared to baseline. Thus, it is now possible with new ingredients to deliver cosmetically elegant photoprotection.

Suggested Readings

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