

Efficacy and Tolerability of a Hand Cream Containing 5% Urea and Sodium Lactate in Patients with Dry Skin and Associated Dermatoses

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Abstract



Hands are exposed to numerous hazards at home, in the work environment, during hobbies and vacations (1). Chemical substances often act as skin irritants and even as skin sensitizers. Especially when injured, the skin of hands can be an important port of entry for many biological agents like bacteria, fungi or viruses. Skin disorders associated with impaired barrier function such as atopic xerosis predispose for developing hand eczema. The hands including fingers are the most common sites of mechanical damage including cuts or abrasions.

Efficacy, skin compatibility and conditioning properties of Eucerin® 5% Urea Hand Cream, containing 5% urea, sodium lactate and glycerin were assessed in 31 healthy volunteers with dry skin as well as in 20 patients with dermatoses of the hands. Tolerability was investigated in a repetitive irritation test conducted with 20 healthy subjects. A further four-week clinical study including 37 patients with hand eczema or xerosis was performed to demonstrate the skin compatibility in diseased skin.

Daily application of the hand cream improved skin moisturization and resulted in a highly significant increase in skin urea.

A reduction of skin roughness was proven by topometry in the treated areas in comparison to untreated. Protection against SDS stress, confirmed by TEWL measurement was also observed.

The skin condition of 92% of the patients with hand eczema or xerosis was normalized or improved at the end of the four-week study period. Most volunteers wanted to continue product use after the end of the study.

We conclude that Eucerin® 5% Urea Hand Cream is well suited and tolerable for patients with sensitive or dry skin, even atopic eczema or hand dermatitis.

Introduction



Because the skin on the hands is especially susceptible to injury, irritants and pathogens, specific skin-care regimens can be highly beneficial for the prevention of irritation or occupational dermatoses like hand eczema. Moisturizing creams containing urea have been reported to improve the physical and chemical nature of the skin surface, with the manifest benefits of smoothing, softening, and making dry skin more pliable (2,3). We evaluated the efficacy of a fragrance free oil-in-water emulsion containing the natural moisturizing factors urea (5%) and sodium lactate (2.5%), and the humectant glycerin. The test product had excellent moisturizing and conditioning properties, demonstrated a protective effect in response to a sodium dodecyl sulphate (SDS) stress, and improved the clinical condition of the hands when used by patients with hand eczema and hand dermatitis with xerosis. The objective of the studies reported here was to test the tolerability, efficacy, skin compatibility and caring properties of a medical hand cream for dry skin containing 5% urea in patients with hand eczema and hand dermatitis.

Materials and Methods



Skin moisturization study

Thirty-one volunteers with healthy skin were enrolled in this study. After enrollment, subjects refrained from the use of topical treatments for a period of 1 week. The test product was thereafter applied twice daily for two weeks. Moisturization, skin roughness and urea content of the skin were assessed at baseline, after 1 day, 1 week, 2 weeks of treatment and 3 days after the last application.

Skin protection study

Twenty volunteers with healthy skin were enrolled for a repetitive irritation test. The product was applied 10 min before the skin was irritated with sodium dodecyl sulphate (SDS) using occlusive patch techniques twice a day. Evaluation of the skin barrier condition was performed by measuring transepidermal water loss (TEWL).

Controlled usage study, subjects with hand eczema and xerosis

Twenty-three subjects with hand eczema and fourteen subjects with hand dermatitis/xerosis completed a four week controlled usage study. The subjects applied the test cream at least twice per day (morning and evening), and as often as needed. Clinical evaluations were made at baseline, and after 2 and 4 weeks of hand cream use for: cracking/fissuring and dryness/scaling (0 to 8 scale), erythema, edema, burning, stinging and itching (0 to 3 scale). In addition, subjects with eczema were evaluated using an Investigator's Global Assessment for Eczema (0 = clear, 5 = very severe). Digital photographs were taken at each of the clinical visits, and subject self-assessment questionnaires were completed after 2 and 4 weeks of treatment.

Results

Skin moisturization study

The test hand cream significantly improved skin moisturization as shown by an increase of corneometer units (fig. 1) and caused a highly significant increase ($p < 0.05$) in the urea content of the skin compared to untreated (fig. 2). In addition, the cream reduced skin roughness (fig. 3), measured by topometry in the treated areas compared to untreated skin.

Skin protection study

A 15% difference in TEWL was observed after 3 days of repetitive exposure to SDS in hand cream treated sites compared to untreated test sites (fig. 4). In addition, the average clinical erythema scores of the hand cream sites were 40% reduced relative to the untreated sites (data not shown), further demonstrating a significant protective effect on the skin against SDS stress.

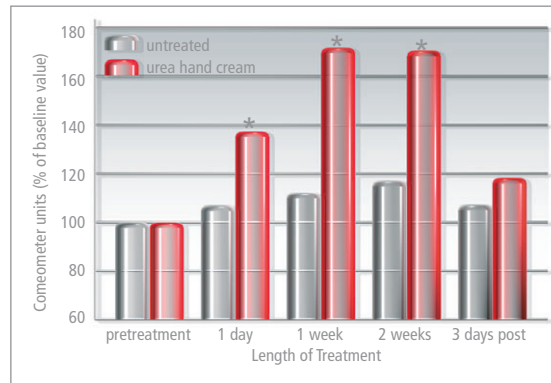


Figure 1:
Improvement in skin hydration

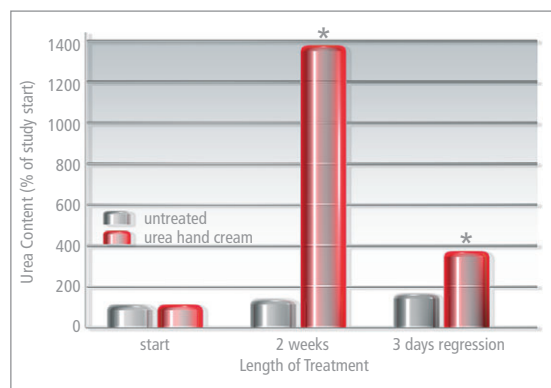


Figure 2:
Increase in skin urea content



Figure 3:
Decrease in skin roughness

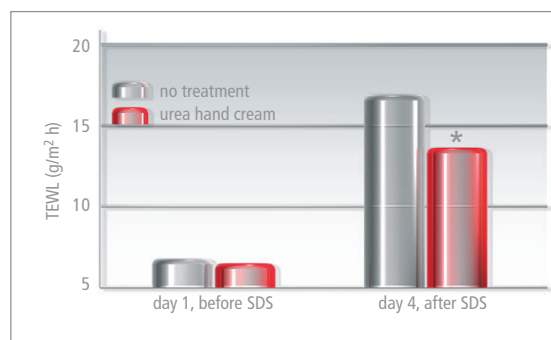
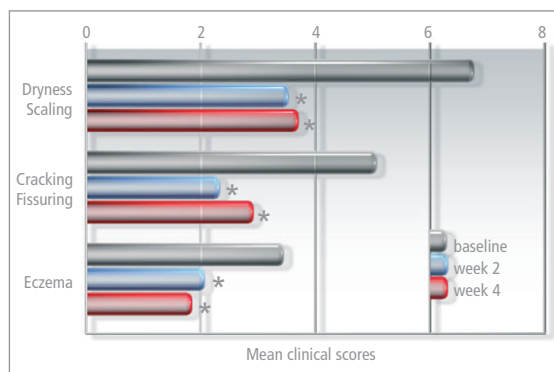


Figure 4:
Protection from SDS stress

Controlled usage study, subjects with hand eczema and xerosis

Significant improvements ($p < 0.05$) in clinical grading scores relative to baseline were observed for dryness/scaling and cracking/fissuring, and the Investigators Global Assessment for Eczema at both week 2 and week 4 (fig 5). Average irritation scores were also significantly reduced relative to baseline at week 2, and negligible by week 4 for itching (0.95 to 0.00), stinging (0.32 to 0.03), and burning (0.35 to 0.00).

Figure 5:
Change in mean
clinical scores with
hand cream use



Digital photographs captured the dry, compromised hand skin condition at the baseline visit, and demonstrated improvements at weeks 2 and 4 that reflected the clinical assessments. Figure 6 shows improvements observed in a subject with hand eczema (baseline, week 2, week 4).

Subjects responded to statements on self assessment questionnaires evaluating moisturization efficacy, tolerability, and application aesthetics. Table 1 gives the number and percentage of subjects that agreed or disagreed with the statement. Responses were overwhelmingly positive and essentially the same for weeks 2 and 4. Twenty-two of twenty-three subjects with hand eczema agreed that their eczema was improved by the urea hand cream. Most subjects wanted to continue using the test product after the end of the study.

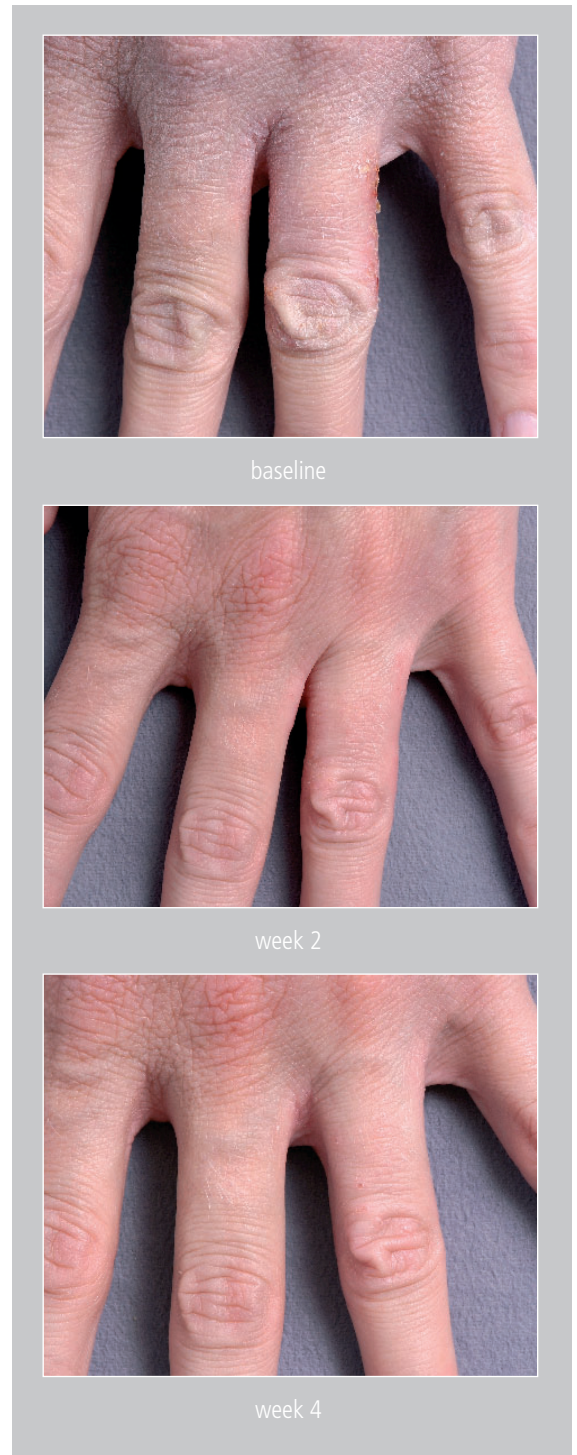


Figure 6: Improvement in skin condition of subject with hand eczema

	Agree Strongly, Agree Somewhat		Disagree Strongly, Disagree Somewhat	
	%		%	
Relieves skin dryness	37	100	0	0
Soothes my cracked hands	34	91.9	0	0
Relieves my tight, cracked hands	34	91.9	0	0
Relieves skin scaling and itch	32	86.5	1	2.7
Repairs dry, irritated hands	34	91.9	0	0
Moisturizes dry, tight skin	36	97.3	0	0
Leaves my hands feeling smooth	37	100	0	0
Leaves skin feeling moisturized	37	100	0	0
Softens my hand skin	37	100	0	0
Is gentle to my hands	37	100	0	0
Does not sting skin	37	100	0	0
Improves my hand eczema (n=23)	22	95.7	0	0
Spreads easily	37	100	0	0
Is not sticky	35	94.6	2	5.4
Is easily absorbed	36	97.3	0	0

Table 1:
Subject self-assessment
questionnaire results at
week 4 (n=37)

Discussion and Conclusion

Hand skin is susceptible to xerosis and dermatitis due to a number of factors including the constant use of the hands, frequent washing, and chemical and irritant exposure. Protective and regenerative therapeutic measures are essential to fortify compromised skin, as irritants and allergens more easily penetrate a damaged barrier. A disturbed barrier function induces a rapid production of pro-inflammatory cytokines by keratinocytes (4), which can potentially cause or aggravate inflammatory conditions such as eczema.

We tested a 5% urea oil-in-water skin cream with sodium lactate and glycerin for its ability to moisturize, protect, and treat healthy and compromised hand skin. Excellent skin hydration effects were observed after the first day and after 2 weeks of usage, and improvements persisted 3 days after ceasing product use. The test cream also had a protective effect on pre-treated skin that was repetitively irritated with SDS. Finally, subjects with hand eczema and general dermatitis exhibited significant improvements in hand skin hydration and condition that was observed clinically and confirmed by the subjects.

In conclusion, appropriate hand care can both treat and prevent common dermatoses like hand eczema.

These studies demonstrate that Eucerin® 5% Urea Hand Cream, specially developed for dry skin conditions of the hands, is excellently suited for patients with sensitive and dry skin, even atopic eczema or hand eczema.

References

1. Estlander T, Jolanki R. How to protect the hands. *Dermatol. Clin.* 1988, 6 (1): 105-114
2. Zhai H, Maibach HI. Moisturizers in preventing irritant contact dermatitis: an overview. *Cont. Derm.* 1998, 38: 241-244
3. Lodén M. et al. Instrumental and dermatologist evaluation of the effect of glycerine and urea on dry skin in atopic dermatitis. *Skin Res. Technol.* 2001, 7: 209-213
4. Lodén M. Skin barrier function: effects of moisturizers. *Cosm. Toil.* 2001, 116 (6): 31-40