Eucerin®

10% Urea Lotion
Concomitant Treatment of Extremely Dry Skin in the Dermatologists Office

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Abstract

Under the conditions of daily use the efficacy and tolerability of a water-in-oil lotion, containing 10% urea and lactic acid as active ingredients, was evaluated in patients with extremely dry and flaky skin throughout the Netherlands.

78 patients (aged 3 to 84 years, mean 43.5 years old) with extremely dry flaky and itchy skin (44.9% atopic eczema, 24.4% xerosis) were recruited through 28 dermatologists in the Netherlands and treated for a mean of 24.1 days.

Marked improvement of itch (94.8%), skin tension (84.9%), dryness (94.6%), desquamation (94.0%) and redness (84.1 %) was observed in patients with a baseline score > 1 at the study conclusion. Tolerability was rated as very good or good by 60.3% of the patients.

The tested product effectively moisturizes as well as relieves dryness, itch, skin tension, redness and desquamation in extremely dry skin conditions. It can also be used concomitant to treatment and supports patients compliance and well-being.

Introduction

Depending upon age, human skin contains up to 90% of water. The average water content in the stratum corneum of healthy subjects is about 54%, increasing to almost 80% in the region of the stratum basale. A decrease in water content in dry skin conditions is caused both by the loss of the ability to bind water as well as by an increased disturbance of the barrier function of the stratum corneum. The water content is regulated by the composition of the stratum corneum lipids as well as by natural moisturising factors (NMF). Urea is present in the NMF of the human horny layer at levels of 3 to 7%. In clinically unaffected skin of patients with e.g. atopic eczema, there is a urea deficit of up to 70% and in affected skin up to 85%. The ability of the horny layer to bind water and its hydration can be improved by the topical application of urea. The kinetic of urea penetration is significantly affected by the skin condition and the type of the vehicle. In the present study we investigated the efficacy and skin compatibility of a water-in-oil lotion containing 10% urea in dermatologists´ offices in the Netherlands.

Materials and Methods

Patients

78 patients (26.9% males and 71.8% females; aged from 3 to 84 years with a mean of 43.5 years) with extremely dry, flaky and itchy skin were recruited in 28 study centres (dermatologists offices) in the Netherlands with a maximum of 5 patients per centre.

Test Product

Eucerin® 10% Urea Lotion contains 10% urea and, additionally, lactic acid as active ingredients in a perfume-free, water-in oil emulsion base.

Test protocol

At baseline (visit 1) demographic data, skin type, medical history, underlying diagnoses and current medication (drug or cosmetic product usage) were recorded.

Skin symptoms (dryness, desquamation, skin tension, itch and erythema) were rated on a 5-point scale (with 1=absent, 2=mild, 3=moderate, 4=severe, 5=very severe) and documented in the case record form. The patients were instructed to apply the test product as often as needed, but at least once a day, to the affected area for a minimum of 14 days.

Skin status was reassessed by the dermatologists 2 to 4 weeks after baseline (visit 2). The area (face, body, extremities) and frequency of application were also listed. The dermatologist rated the tolerability of the test product. Patients were asked to evaluate skin hydration, smoothness, absorption and scent of the product on a 4-point scale.

All data were collected between October 2005 and January 2006.

Results

The patients presented with the following diseases at the time of study start: 44.9% had atopic eczema, 26.9% xerosis, 10.3% contact dermatitis, 9.0% psoriasis, 10.1% other dermatoses (multiple entries possible). At baseline 51 patients (65.4%) applied concomitant drugs or cosmetic products.

Table 1 displays an overview of the distribution of the individual symptoms (score > 1) at the study start.

Table 1: Presence of symptoms at baseline visit

Symptoms	n	%*
Dryness	77	98.7
Desquamation	70	89.7
Itch	60	76.9
Skin tension	55	70.5
Erythema	46	59.0
*78= 100% (allowing for multiple entries)		

Table 2 illustrates the frequency of application of the test product. The most common application scheme was daily (52.6%) followed by twice daily (30.8%).

Table 2: Application scheme

Time interval	n	%
Twice daily	24	30.8
Once daily	41	52.6
Six times a week	2	2.6
Five times a week	3	3.8
Every other day	3	3.8
Every third day	1	5.1
Missing	4	5.1
Total	78	100.0

The lotion was applied to the arms in 71 patients (91%) and to the legs in 64 patients (82.1%). The body was the primarily treated site in 53 patients (67.9%) and the face in 19 patients (24.4%). The most frequent simultaneous application areas were body, legs and arms.

Table 3 depicts the time interval between the baseline and final visit and thus the duration of treatment with the test product.

Table 3: Duration of treatment

Time interval	n	%
1 to 2 weeks	6	7.7
2 to 3 weeks	19	24.4
3 to 4 weeks	24	30.8
> 4 weeks	28	35.9
Missing	1	1.2
Total	78	100.0

At the final visit, 19.2% of the patients were completely free of symptoms, 71.8% showed an improvement of overall skin condition and 6.4% no changes. Only 2.6% (2 patients) demonstrated an impairment of their skin condition.

At baseline, dryness as a symptom was reported in 77 patients (98.7%) whereas at the final visit this number decreased to 61 (78.2%). In 70 patients there was an improvement of dryness, and in 1 patient (1.4%) the severity of dryness increased. 94.6% of patients with dryness at baseline showed an improvement, and the mean score decreased from 3.8 at baseline to 2.2 at the final visit. Figure 1 demonstrates the change of dryness at baseline compared to the final visit.

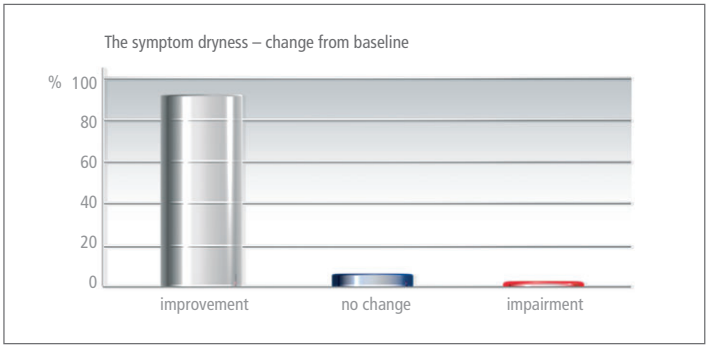

Figure 1: The symptom dryness – change from baseline

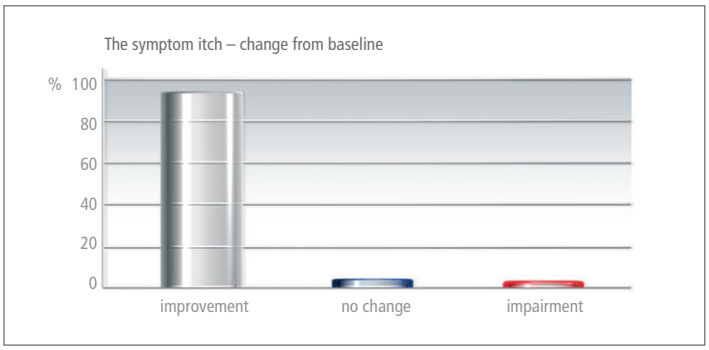

Figure 2: The symptom itch – change from baseline

Considering the number of patients with desquamation at baseline (n=70), 94% showed an improvement, no patient experienced a worsening of this symptom. Skin tension was similarly improved in 84.9% of the patients with this symptom at the start of the study (n=45). Redness was relieved in 37 patients (84.1%) of the 44 with this symptom at baseline.

Itch was reported at baseline in 60 patients (76.9%) whereas at the final visit itch decreased in 27 (34.6%). In 55 patients an improvement of itch was noted, whereas in 1 patient (1.4%) the grade of itch intensity increased. 94.8% of patients with itch at baseline showed an improvement, and the mean score decreased from 2.1 at baseline to 1.4 at the final visit. Figure 2 demonstrates the intensity of itch at baseline compared to the final visit.

The dermatologist also rated the overall efficacy and tolerability of the lotion on a 4-point scale (very good, good, moderate and poor). In 58 patients (74.4%) the efficacy was rated to be good or very good, only in 2 patients as poor. In 16 patients no rating was available.

The tolerability of the product was judged to be good or very good in 27 patients (60.3%) and in 4 patients as poor. One of these patients stopped using the product due to an allergic reaction (redness, itching and burning). In 10 patients ratings were missing.

All product properties, with the exception of "scent", were rated "good" or "very good" by more than 78% of the patients. The scent of the perfume-free product was rated "good" or "very good" by 53.9% of the patients.

A subgroup analysis of 34 patients with atopic eczema showed comparable improvement rates concerning the typical dry skin symptoms (dryness 88.2%, scaliness 93.6%, skin tension 80.8%, itch 90.3%, redness 84%).

Discussion and Conclusion

Various studies have shown that the hydration of the skin can be improved by the topical application of urea. The type of vehicle plays a major part in this. Urea in o/w emulsions rapidly penetrates into the horny layer and achieves high concentrations for short periods of time. In w/o emulsions penetration occurs more slowly. However, after a prolonged period of exposure similar concentrations of urea are reached. If the aim is to stabilise or restore the function and structure of the horny layer in chronic dry skin conditions the application of a w/o type emulsion is more advisable.

The presented study showed that treatment with Eucerin® 10% Urea Lotion, a water-in-oil emulsion, over a period from 2 weeks up to 4 weeks resulted in an improvement of clinical symptoms such as dryness, desquamation, skin tension, itch and redness.

Eucerin® 10% Urea Lotion proved to be a well tolerated formulation in patients with atopic eczema or xerosis and can also be recommended adjunct to dermatological therapy.

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