

# Clinical Trial on Aveeno Skin Relief Moisturizing Lotion in Patients with Itching Accompanied by Skin Lesions and Xerosis

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## ABSTRACT

**Background:** Itch associated with cutaneous xerosis is a common condition, which can be effectively treated with the use of emollients combined with hydration therapy. The aim of our study was to evaluate the efficacy and tolerability of a new lotion containing menthol and colloidal oatmeal in patients with itch and cutaneous xerosis.

**Patients and Methods:** Fifty-four patients with pruritus of different origin associated with lesions as erythema, desquamation, scratching, and lichenization were treated with Aveeno Skin Relief Moisturizing Lotion once daily for 3 weeks. Efficacy and tolerability were evaluated by comparison of changes from baseline in clinical appearance, hydration, and pH.

**Results:** After treatment, clinical examination, and the self-administered questionnaire revealed a significant

improvement of cutaneous lesions including erythema, scaling, scratching lesions, lichenization, and pruritus in 52 of 54 treated patients (96%). Complete regression of cutaneous lesions and pruritus was achieved in 48 of 54 (88.9%) patients; whereas a partial remission was observed in 4/54 (7.4%) subjects and no improvement in 2/54 (3.7%) subjects. An increase of cutaneous hydration of 35.9% after 1 week treatment and of 45.7% after 3 weeks treatment was observed; those increments were associated with a simultaneous decrease of cutaneous pH: -4.0% after one week and -6.3% after 3 weeks treatment. The lotion was well tolerated by all patients.

**Conclusions.** Based on our experience, Aveeno Skin Relief Moisturizing Lotion appears to be an effective moisturizing emollient that reduces pruritus in subjects with xerosis.

## INTRODUCTION

It has been well established that patients with dry skin conditions have a defect in skin barrier function even on

areas of skin that have a normal appearance, and emollients have been widely used for the long-term treatment of dry skin conditions such as eczema and psoriasis.<sup>1-3</sup> Emollients exert their skin softening and moisturizing effect within the stratum corneum. They help to restore the epidermal barrier and thereby prevent the penetration of environmental triggers that may cause an inflammatory reaction. Moreover, they may also have a direct antipruritic/anti-inflammatory effect on the skin.<sup>4</sup>

Itch is among the main symptoms of several dermatological diseases such as lichen simplex, lichen planus and atopic dermatitis.<sup>5</sup> Pruritus is often the hardest symptom to treat, causing the patient severe discomfort. However, the therapeutic arsenal to reduce itch is rather limited and the effect of the various treatments to date is highly variable.<sup>6</sup>

Like pain, itch can be of central (neuropathic, neurogenic, or psychogenic) or peripheral (dermal) origin.

Neuropathic itch can originate as a result of damage to the nervous system and has been reported in postherpetic neuralgia, multiple sclerosis, cerebral tumors or thrombosis. Neurogenic itch is induced centrally, without neural damage and is often associated with increased opiodergic tone caused by the accumulation of endogenous opioids. Psychogenic itch can be associated with psychiatric disorders as in parasitophobia.<sup>7-8</sup>

Peripheral itch, originating in the skin, can be due to inflammation, dryness, or other skin damage and is defined "pruritoceptive." It is induced by stimulation of the free nerve endings of specialized C-fibers by one or more pruritogens. These C-fibers are anatomically identical but functionally distinct to those associated with the mediation of pain. Several mediators of cutaneous itch have been identified and many endogenous chemicals are locally pruri-

togenic when injected in the skin, such as amines, proteases, growth factors, neuropeptides, opioids, eicosanoids and cytokines.<sup>9</sup> Causes of systemic itch of peripheral origin include uremia, cholestasis, hyperthyroidism, HIV infections and some blood disorders, eg, polycythemia vera, Sezary's syndrome, Hodgkin's lymphoma, and leukemia. Itch is also a very common manifestation of several cutaneous diseases, including xerotic eczema, atopic dermatitis, and contact dermatitis.<sup>10-11</sup> It has been observed that itch is very often associated with conditions of cutaneous xerosis.

Although anti-inflammatory therapies such as topical glucocorticoids, and more recently, topical immunosuppressive agents (tacrolimus, ascomycin, mycophenolate mofetil), are considered mainstays of itch therapy, prevention of cutaneous xerosis and rehydration of dry skin represent critical components for successful management of patients with pruritus. Use of effective emollients combined with hydration therapy help to restore and preserve the stratum corneum barrier and might decrease the need for topical corticosteroids.<sup>12</sup>

The aim of our study was to evaluate the efficacy and tolerability of a new lotion containing colloidal oatmeal and menthol, used once a day for 3 weeks, in patients with itch associated with cutaneous xerosis.

## **PATIENTS AND METHODS**

This open study was performed to evaluate the efficacy and tolerability of Aveeno Skin Relief Moisturizing Lotion in subjects with itching accompanied by skin xerosis and erythema, desquamation, scratching lesions, and/or lichenization. The study was conducted at the Departments of Dermatology, University of L'Aquila and University of Rome "Tor Vergata" from January to July 2003.

Personal and family histories for allergic pathologies and atopic dermatitis were registered. Two weeks before starting the trial, all patients discontinued previous topical or systemic treatments used for possible skin pathologies.

Aveeno Skin Relief Moisturizing Lotion was kindly provided by Johnson & Johnson Italy. The lotion was used as the only treatment once a day for 3 weeks. Patients were allowed to use neutral cleansing daily.

The study included a screening visit (T0) and a treatment period with regular visit after 1 (T1) and 3 weeks (T3).

Clinical evaluation of skin lesions was performed at each time point and the presence of erythema, desquamation, scratching lesions, and lichenization was scored as 0 = absent, 1 = mild, 2 = moderate.

Before and after treatment, lesions of each subject were photographed and pH and skin hydration measurements were performed using a SM CM PH Combi 3 instrument (G. F. Secchi, Italy). The pH of healthy skin can vary from acidic (3.5-4.4), normal (4.5-5.5), or alkaline (> 5.6); the level of corneal stratum hydration of healthy skin is < 50 for very dry skin, 50-60 for dry skin, and > 60 for normally hydrated skin.

At the end of the study all subjects completed a self-administered questionnaire for the evaluation of itching with 10 questions each quantified with 0-10 visual analogue scale.

In order to evaluate treatment efficacy, results were analyzed by analysis of variance. Statistical analysis was performed using STATA software (Stata Corporation, College Station, Texas) and a *P* value < 0.05 was considered statistically significant.

## RESULTS

A total of 54 patients (20 male and 34 female, mean age 46 years, range: 12-79 years) who had itching (mean score 5.8)

and xerosis were included in this study. Itching was accompanied by erythema in 13 patients, desquamation in 49, scratching lesions in 30, and lichenization in 10. Twenty-eight patients had allergies, 12 had atopic dermatitis, and 10 were in dialysis.

The 54 subjects completed the 3 weeks treatment with Aveeno Skin Relief Moisturizing Lotion in a compliant manner, as ascertained by questioning at baseline and at the end of the study.

After 3 weeks of treatment, clinical examination revealed a significant improvement of cutaneous lesions including erythema, scaling, scratching lesions, and lichenification, as well as pruritus in 52/54 (96%) of treated patients. Complete regression of cutaneous lesions and pruritus was achieved in 48/54 (88.9%) patients, and a partial remission was observed in 4/54 (7.4%); no improvement was observed in 2/54 (3.7%). Self-administered questionnaires revealed a significant decrease of pruritus:  $\pm$  44.8% after the first week and -73.5% after 3 weeks of treatment ( $P < 0.001$ ) (Table 1).

The 2 patients who showed no improvement were affected by advanced chronic renal failure treated with hemodialysis.

An increase of cutaneous hydration of 35.9% was observed after 1 week treatment and of 45.7% after 3 weeks of treatment ( $P < 0.001$ ) (Table 2).

Results of pH measurements revealed a simultaneous decrease of cutaneous pH: -4.0% after 1 week and -6.3% after 3 weeks treatment ( $P < 0.001$ ) (Table 3).

No intolerance reactions to Aveeno Skin Relief Moisturizing Lotion have been reported.

## DISCUSSION

Itch, also known as pruritus, is one of the major complaints in dermatologic

**Table 1.** Improvement of Itching After 1 Week and 3 Weeks of Treatment.

Itching	No change (n)	Improvement (n)	Mean score	Score variation	Significance (P)
T0	-		5.80		
T1	12	42	3.20	-44.8	> 0.001
T2	1	52	1.43	-75.3	> 0.001

**Table 2.** Improvement of Hydration After 1 Week and 3 Weeks of Treatment

Hydration	Mean score	Variation	Signifi- cance (P)
T0	29.4	-	
T1	45.8	+35.9	> 0.001
T2	54.2	+45.7	> 0.001

**Table 3.** Reduction of pH After 1 Week and 3 Weeks of Treatment

pH	Mean score	Variation	Signifi- cance (P)
T0	5.7	-	
T1	5.5	-4.0	> 0.001
T2	5.3	-6.3	> 0.001

and internal diseases. Although it can be extremely distressing and as disabling as severe pain; its pathophysiology is still not completely understood. Itch and pain seem to be transmitted by the same nerve fibers, the slow conducting unmyelinated C fibers. The existence of specialized itch fibers remains to be documented. Itch can appear either after direct mechanical stimulation of the itch receptors or through activation or release of mediators which would stimulate the itch receptors.<sup>13</sup>

Itch is often defined as a sensation that induces the urge to scratch. Scratching, in turn, gives instant relief from itch, presumably through activation of mechanical nociceptors in the skin but unfortunately, scratching will exacerbate the underlying skin condition by inducing additional lesions in the skin.<sup>14</sup>

Several topical drugs are currently used in the treatment of itch. Among them, capsaicin, isolated from pepper plants of the genus *Capsicum*, has been demonstrated to deplete substance P from C-fibers when applied repeatedly

and to reduce both pain and itch. Calamine is a lotion containing phenol 0.5% used in the treatment of non-specific itch.

Recent studies have demonstrated that, even though oral administration of aspirin seems to have little or no effect on clinical itch, topical aspirin has an antipruritic effect in experimentally induced itch.

Polidocanol is a non-ionic surfactant with local anesthetic properties. Creams containing 3% polidocanol have been successfully used in the treatment of atopic dermatitis.<sup>15-16</sup>

In this clinical trial we tested the efficacy of a lotion containing colloidal oatmeal and menthol, in reducing itch of various origin.

Colloidal oatmeal is extracted from seeds of *Avena sativa*, an annual plant of Graminae. It contains essential fatty acids, flavonoids, phospholipids, and sterols that exert a moisturizing and emollient activity associated with a protective action on the skin, maintaining the hydrolipidic film of the surface, and

reducing the transepidermal water loss (TEWL). Insoluble proteins contained in colloidal oatmeal have buffering properties, maintaining cutaneous pH at physiologic values. In addition, a lenitive and anti-inflammatory action is due to flavonoids that inhibit the synthesis of prostaglandins.<sup>17</sup>

Menthol is a naturally occurring monocyclic terpene found in the oil of the mint tree *Mentha arvensis*. *Mentha piperita* oil is currently used in cosmetic formulations as a fragrance component and is composed primarily of menthol and menthone. Menthol is well known for its cooling effects and its mint flavor and odor, which are the basis of the majority of its uses, such as nasal sprays, cough drops, mouthwashes and sprays. In addition, short-term antinociceptive effects of menthol are well known and it has been widely used in several topical antipruritic products. It has been demonstrated recently that menthol, after topical application, causes a feeling of coolness due to the stimulation of “cold” receptors by inhibiting Ca<sup>++</sup> currents of neuronal membranes. Menthol has also anti-inflammatory properties, by inhibition of release of leukotrienes, prostaglandins and interleukines from monocytes and of serotonin and neuropeptides.<sup>18-20</sup>

Our study demonstrated that the combined effect of the substances contained in Aveeno Skin Relief Moisturizing Lotion, in particular colloidal oatmeal and menthol, exert an excellent moisturizing, emollient, and anti-itching action. Reduction of itching was reported by most patients through self-administered questionnaires. Only 2 treated patients showed no improvement after application of the tested product. Both of them were affected by advanced chronic renal failure. Xerosis and uremic pruritus are very frequent in hemodialysis patients, and pruritus is strongly related to the severity of renal

failure and to the duration of hemodialysis.

The emollient properties of the Aveeno Skin Relief Moisturizing Lotion were evaluated by its ability to increase cutaneous hydration. Those evaluations have shown a significant increase in cutaneous hydration associated with a normalization of pH. Furthermore, at the end of the study, a progressive restoring of the physiologic skin conditions was also seen. The simultaneous improvement of pruritus can be related both to the antipruriginous properties of menthol and to an adequate rehydration of the skin.

In conclusion, based on our study, Aveeno Skin Relief Moisturizing Lotion revealed a good tolerability and excellent moisturizing and anti-itching properties. Aveeno Skin Relief Moisturizing Lotion, might therefore be considered an effective treatment in patients with pruritus associated to cutaneous xerosis, either alone or as an adjunctive therapy to corticosteroids and/or antihistamines.

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