



SCIENTIFIC REVIEW OF AN
OAT BASED SKINCARE REGIMEN
FOR PATIENTS WITH ATOPIC SKIN



FORWARD

Atopic dermatitis is an inflammatory skin disease accompanied by a variety of signs and symptoms including heightened skin sensitivity, intense pruritus, xerosis and even skin lichenification in the more advanced stages. Patients with atopy have an impaired skin barrier thus allowing a greater permeation of irritants and allergens. Even though a number of exogenous factors can trigger a patient with atopy to flare, a gentle and moisturizing daily skin care routine is important for proper hydration and maintenance of a healthy skin barrier. Body cleansers and moisturizers not only need to be free of potential irritating ingredients, allergens and fragrances but also should be formulated with ingredients that protect, hydrate and provide benefits to skin in strengthening an already compromised barrier. Special care needs to be taken when choosing ingredients and formulations need to be reviewed by dermatologists who are experts in both allergy and an atopic population. Proper safety, allergy and tolerance testing is imperative to assure that the regimen is safe and well tolerated by those with atopic dermatitis.

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1. CLINICAL TRIAL TO DETERMINE THE BENEFIT OF AVEENO® ECZEMA THERAPY ITCH RELIEF BALM ON DRY, ITCHY SKIN OF ADULTS AND CHILDREN WITH ATOPIC DERMATITIS (n=39 patients aged 12+ with mild to moderate atopic dermatitis)

OBJECTIVE

To evaluate the efficacy of an over-the-counter (OTC) 1% colloidal oatmeal skin protectant balm in adults and children with mild-to moderate atopic dermatitis (AD).

STUDY DESIGN

Fifty-two adults and children aged 12+ years with mild to moderate atopic dermatitis (score 3.0 and 7.5 inclusive per Rajka-Langeland severity index) and mild-to-moderate itch (VAS Itch Assessment = 4.0) completed this multi-center, 7-day, randomized (3:1), evaluator-blinded, 2-arm clinical study.

EFFICACY MEASURES

Primary endpoints:

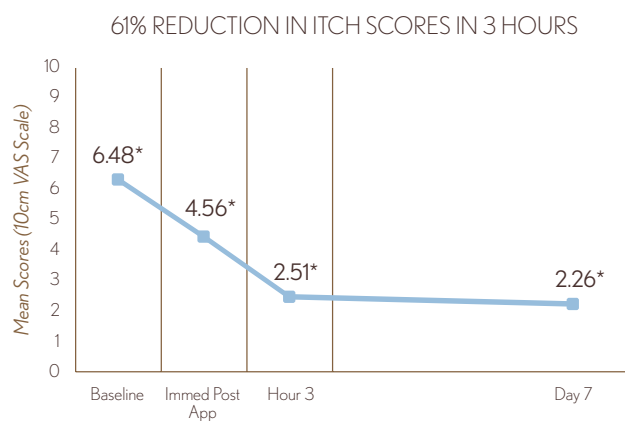
- Itch Assessment (10-cm VAS scale) at baseline, immediately post-application, Hours 1, 2, 3, 4, 5, and 6 post-application, and Day 7

Secondary endpoints:

- Corneometer readings at baseline, immediately post-application, Hours 1, 2, 3, 4, 5, and 6 post-application, and Day 7
- Participant Questionnaires at baseline, immediately post-application, Hours 4, 5, and 6 post-application, and Day 7

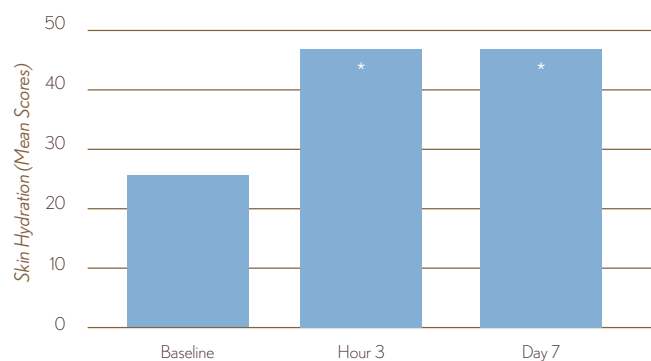
RESULTS

CLINICALLY PROVEN TO RELIEVE DRY, ITCHY, IRRITATED SKIN DUE TO ECZEMA¹



* Significant improvement ($p < 0.001$)

IMMEDIATE AND LONG-LASTING MOISTURIZATION (CORNEOMETER)¹



n = 39 patients with mild to moderate AD

PATIENT ASSESSMENT AT DAY 7:

- 75% felt they slept better due to less itching
- 100% felt they were less distracted by their itchy skin

CONCLUSIONS:

- The results of this study indicate that AVEENO® Eczema Therapy Itch Relief Balm was effective and well tolerated in adults and children aged 12 years and older with mild to moderate atopic dermatitis and mild to moderate itch.
- AVEENO® Eczema Therapy Itch Relief Balm significantly improved itch immediately after the first application, which lasted up to 6 hours; in addition, significant itch improvements were observed after 7 days of product use.
- AVEENO® Eczema Therapy Itch Relief Balm also significantly improved skin moisturization after the first application, which lasted up to 6 hours; improved skin moisturization was also found on Day 7.
- Statistically significant differences were observed in favor of the AVEENO® Eczema Therapy Itch Relief Balm at all timepoints compared to the control.
- AVEENO® Eczema Therapy Itch Relief Balm was well tolerated and subjects achieved strong agreement to product experience questionnaire statements related to improvements in the feel of skin and lifestyle.

2. CLINICAL TRIAL TO EVALUATE THE EFFICACY OF AVEENO® BABY ECZEMA THERAPY NIGHTTIME BALM IN THE MANAGEMENT OF MILD TO MODERATE ATOPIC DERMATITIS IN INFANTS AND TODDLERS (n=17 patients aged 6 to 47 months with mild to moderate atopic dermatitis)

OBJECTIVE

To evaluate the efficacy of an over-the-counter (OTC) colloidal oatmeal skin protectant balm in children with mild-to-moderate atopic dermatitis (AD) and sleep disturbances.

STUDY DESIGN

Seventeen patients between the ages of six and forty-seven months with mild to moderate atopic dermatitis, at least 1 active lesion and reported “sleep disturbances” completed this single-center, randomized, 14-day, 2-arm clinical study.

EFFICACY MEASURES

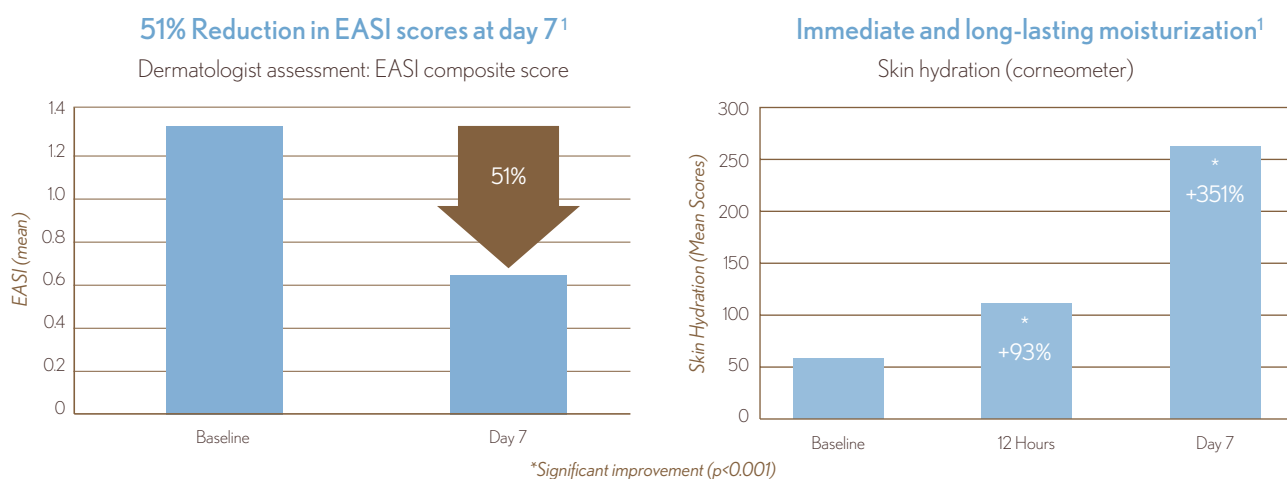
Primary endpoints:

- Corneometer immediately post treatment & 12 hours post-treatment

Secondary endpoints:

- EASI and IGADA, Dryness Scale, and Corneometer at 24 hours post-treatment, Days 3, 7 and 14
- Brief Infant Sleep Questionnaire (BISQ), Days 7 and 14
- Caregiver Itch Assessments at Days 3, 7 and 14
- Caregiver Questionnaire immediately post application, Days 3, 7 and 14

RESULTS



CAREGIVER ASSESSMENT:

- 42% relief in itch at 2 weeks
- 90% said their baby/toddler’s overall skin looked smoother after 1 week
- 100% felt their baby/toddler’s overall skin looked healthy in just 2 weeks
- 100% would recommend AVEENO® BABY ECZEMA THERAPY NIGHTTIME BALM to other moms

CONCLUSIONS:

- The results of this study indicate that AVEENO® Baby Eczema Therapy Nighttime Balm was effective and well tolerated in infants and toddlers aged 6-47 months with mild to moderate atopic dermatitis and sleep disturbances.
- AVEENO® Baby Eczema Therapy Nighttime Balm significantly increased skin moisturization immediately and at 12hrs after only one product application; improved moisturization was also observed at all remaining timepoints (24 hours, and Days 3, 7, and 14).
- AVEENO® Baby Eczema Therapy Nighttime Balm subjects also showed significant improvements in overall disease severity and extent of disease, skin dryness, caregiver perception of itch, and parameters of sleep quality. Caregiver questionnaires noted significant improvements in overall and eczema skin appearance as well as caregiver QOL.
- AVEENO® Baby Eczema Therapy Nighttime Balm was well tolerated as there were no reported, product-related adverse events within this group.
- These results suggest AVEENO® Baby Eczema Therapy Nighttime Balm provides patients, caregivers, and dermatologists with an alternative therapy to improve eczema symptoms and overall quality of life.

3. ASSESSMENT OF AVEENO® ECZEMA THERAPY MOISTURIZING CREAM THROUGH A MULTI-CENTRIC CLINICAL STUDY ON INFANTS, CHILDREN AND ADULTS WITH ATOPIC DERMATITIS (n=71 patients in total aged 6 months to adult ; topical steroid data based on n=19 patients who previously used topical steroids during the washout period) Nollent V., Lopes M.J., Katsarou A., Gelmetti C., Bertin C. Scientific Poster presented at the EADV, Prague 2012.

OBJECTIVE

To assess the efficacy of AVEENO® Eczema Therapy Moisturizing Cream in improving the signs of atopic skin and improving quality of life. This multi-centric study was completed by 71 patients at three centers in Greece, Portugal and Italy.

STUDY DESIGN

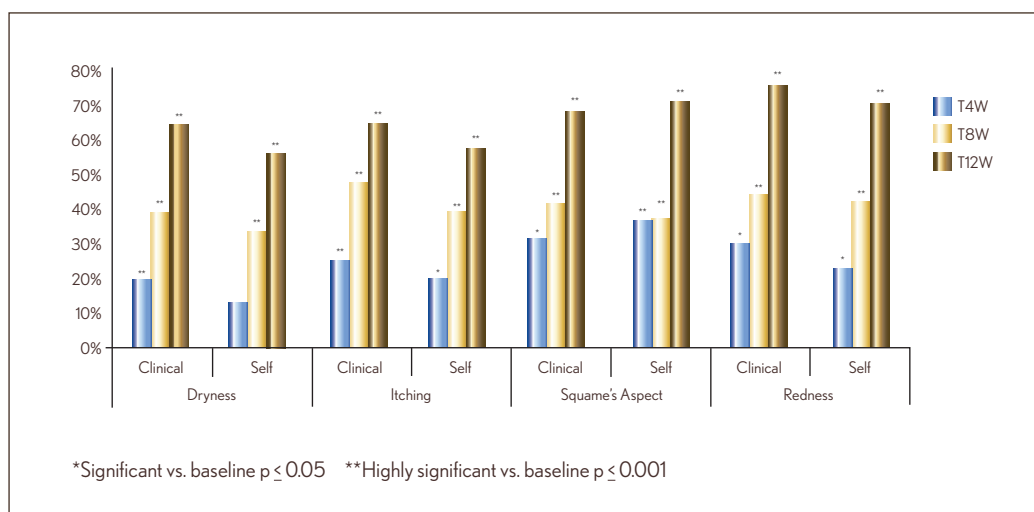
99 patients between the ages of six months and adulthood with mild-to-moderate atopic dermatitis were enrolled in this open 12 week multi-centric study in Greece, Portugal and Italy. 71 patients completed the study. Evaluations included SCORAD, Clinical grading, instrumentation, Self-assessment and Quality of Life questionnaires at 4, 8 and 12 weeks.

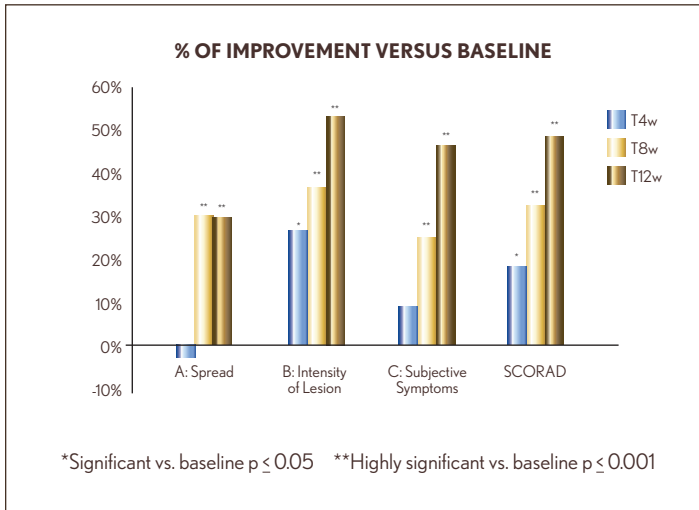
RESULTS

Use of AVEENO® Eczema Therapy Moisturizing Cream resulted in significant improvement in skin conditions parameters. At week 12:

- 100% of patients saw improved skin hydration
- 75% improvement in redness
- 68% improvement in scaling
- 65% improvement in dryness
- 64% improvement in itching

CLINICAL AND SELF GRADING - % IMPROVEMENT VERSUS BASELINE



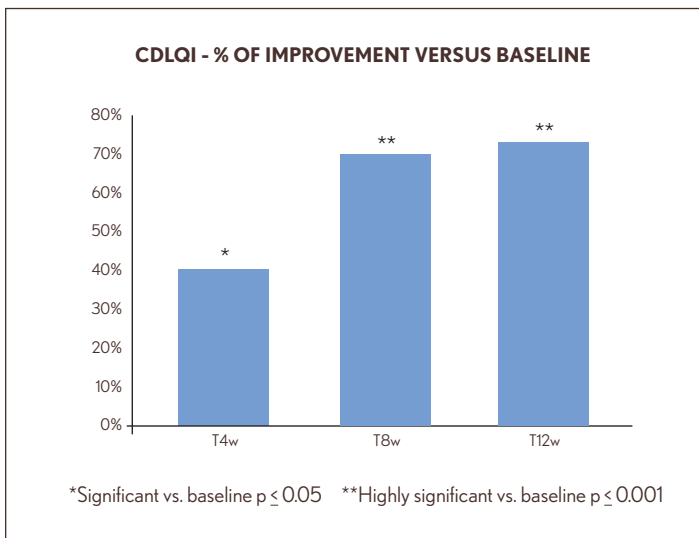


SCORAD

48% improvement in SCORAD ($p \leq 0.001$) by 12 weeks

More than 90% of patients had significant improvement in SCORAD at Week 12

SCORAD also contains an element of QoL with the subjective signs of pruritus and sleep loss, therefore such an improvement in SCORAD is an indirect measure of improvement in QoL



QUALITY OF LIFE

The CDLQI showed a significant improvement as soon as 4 weeks

Children reported a 72% improvement in Quality of Life scores at 12 weeks

CORTICOSTEROID SPARING

- 39% reduction in corticoid usage assessed through weight measures at 12 weeks
- 63% of patients felt they used fewer corticoids/immunomodulators after using AVEENO® Eczema Therapy Moisturizing Cream for 4 weeks

TOLERABILITY

AVEENO® Eczema Therapy Moisturizing Cream was well tolerated by 96% of patients after 3 months of use. Patients were highly satisfied with AVEENO® Eczema Therapy Moisturizing Cream texture and absorption, which can lead to increased compliance.

CONCLUSIONS

In this multi-center study, AVEENO® Eczema Therapy Moisturizing Cream demonstrated excellent efficacy in the improvement of dryness, erythema, itching and scaling (clinical parameters of atopic skin) at four weeks and these continued to increase over the course of the trial. SCORAD significantly improved over the course of the study period as the skin condition improved. Consequently, subjects felt less need to use medication. All of those improvements led to an improvement in quality of life parameters.

AVEENO® Eczema Therapy Moisturizing Cream was well tolerated in all age groups and patients were satisfied with the moisturizer's texture and absorption which leads to increased compliance, an important factor in the management of atopic eczema.

4. CLINICAL ASSESSMENT OF AVEENO® ECZEMA THERAPY TO ALLEVIATE DRY TO VERY DRY SKIN OR SKIN PRONE TO ATOPIC DERMATITIS AND TO IMPROVE THE PATIENTS' QUALITY OF LIFE (n=75) Study sponsored by Johnson & Johnson do Brasil ind.Com. Prod. Para Saúde Ltda. Principal Investigator. Dr Lucia Helena Favaro de Arruda. Preliminary data presented by Dr Maria João Lopes at the ESPD Congress, Istanbul 2012.

OBJECTIVE

To assess the efficacy of AVEENO® Eczema Therapy Moisturizing Cream in relieving dry and very dry skin or skin prone to atopic eczema and consequently to improve patients' quality of life. This study was completed by 75 patients at a center in Brazil.

STUDY DESIGN

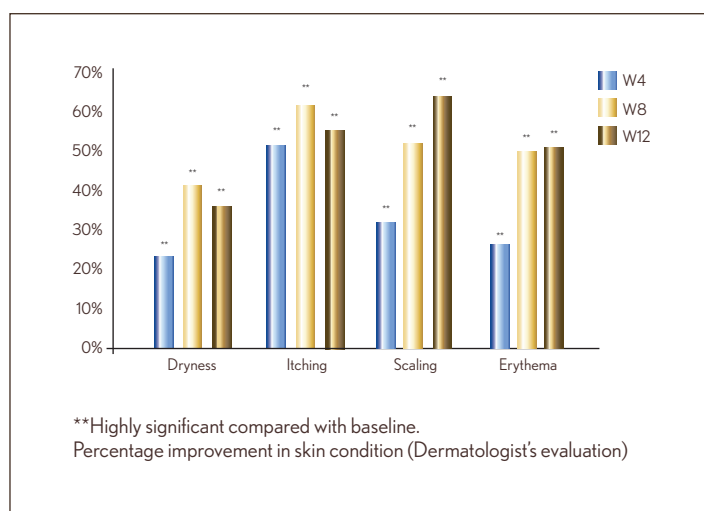
75 patients between the ages of 2 and 65 years old with mild-to-moderate atopic eczema with or without topical steroids/ immunomodulators/antihistamines completed this 12 week open study carried out in Brazil (Campinas, São Paulo State). Evaluations included SCORAD, Clinical grading instrumentation, Self-assessment and Quality of Life questionnaires at 4, 8 and 12 weeks.

RESULTS

EFFICACY

When the results from the study are pooled at each time point a statistically significant improvement in all four clinical parameters, dryness, erythema, itching and scaling is seen from four weeks of use.

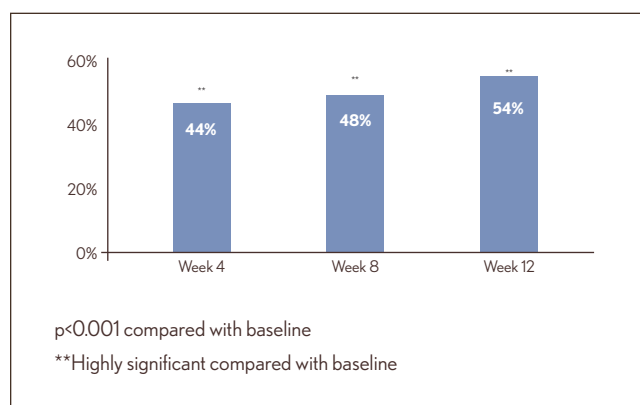
PERCENTAGE IMPROVEMENT IN CLINICAL PARAMETERS OF ATOPIC SIGNS CLINICAL GRADING - COMPARED WITH BASELINE VISIT



SCORAD

SCORAD, a composite measure of overall skin condition, continued to improve significantly over the 3 months of the trial in all age groups. A percentage improvement of 44% was seen at week 4, up to 48% at week 8 and continued to improve, reaching 54% after 3 months. SCORAD contains an element of QoL with the subjective signs of pruritus and sleep loss, therefore such an improvement in SCORAD is also an indirect measure of improvement in QoL.

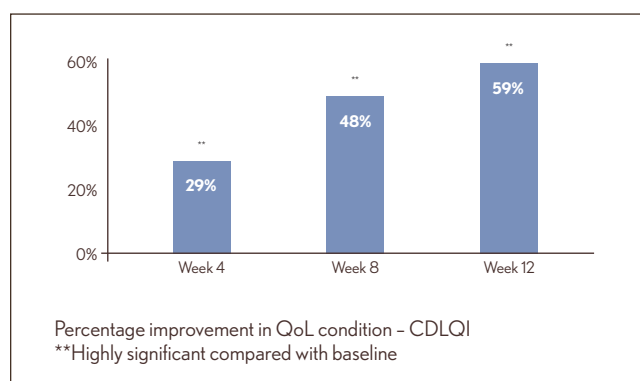
PERCENTAGE IMPROVEMENT IN SCORAD



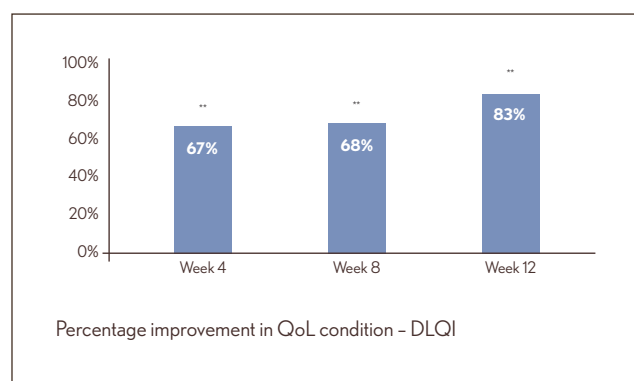
QUALITY OF LIFE

The use of AVEENO® Eczema Therapy Moisturizing Cream had a positive impact on the QoL of subjects in the trial. This is clearly demonstrated by the results of QoL questionnaires. Children aged 5 to 16 years used the CDLQI. Adults used the DLQI. A continuous improvement in QoL was seen for children through the course to a highly significant improvement of 59% by 12 weeks, the end of the trial period. After four weeks a highly significant improvement of 67% in QoL was assessed for adults and continued to a 83% improvement after 3 months of usage.

PERCENTAGE IMPROVEMENT IN QoL FOR CHILDREN 5 TO 16 YEARS-OLD



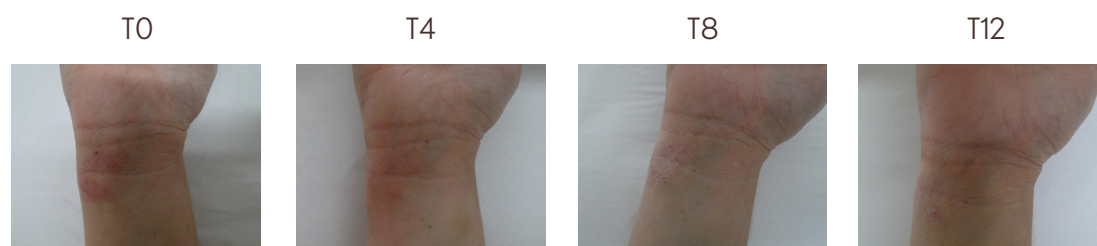
PERCENTAGE IMPROVEMENT IN QoL FOR ADULTS



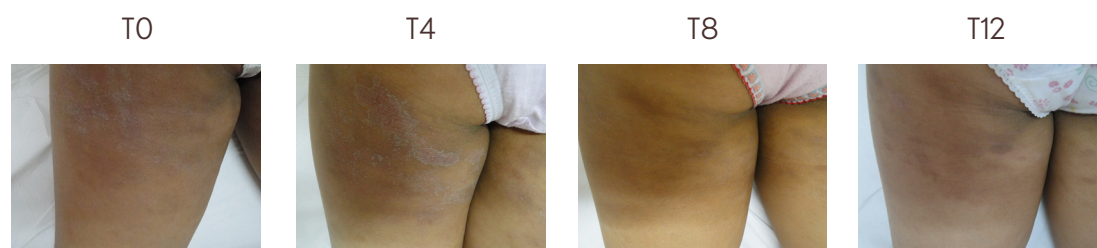
CLINICAL IMPROVEMENTS

Clinical improvements were also assessed by photographs. The photographs were taken at each visit to show the improvement in skin condition.

Illustration with examples of results obtained on 2 patients



Female aged 32 years



Female aged 5 years

CONCLUSIONS

Results from this open clinical study with daily use of AVEENO® Eczema Therapy Moisturizing Cream show the improvement of dryness, erythema, itching and scaling (clinical parameters of atopic skin) at four weeks and continued to improve over the course of the trial. SCORAD significantly improved over the course of the study period as skin condition improved. Consequently, subjects felt they used less medication. All of those improvements led to an improvement in quality of life parameters.

AVEENO® Eczema Therapy Moisturizing Cream was well tolerated in these age groups and patients were satisfied with the moisturizer's texture and absorption which leads to increased compliance, an important factor in the management of atopic eczema.

5. GREEK OBSERVATIONAL STUDY OF AVEENO® ECZEMA THERAPY MOISTURIZING CREAM AND AVEENO® BABY CLEANSING THERAPY MOISTURIZING WASH (n=1607) Preliminary data presented Dr Kyriakos Volonakis at the ESPD Congress, Istanbul 2012.

OBJECTIVE

To assess the efficacy and tolerability of AVEENO® Eczema Therapy Moisturizing Cream and AVEENO® Baby Cleansing Therapy Moisturizing Wash in improving the signs of atopic skin and improving quality of life. This observational study was conducted by 46 researchers in Pediatrician offices throughout Greece.

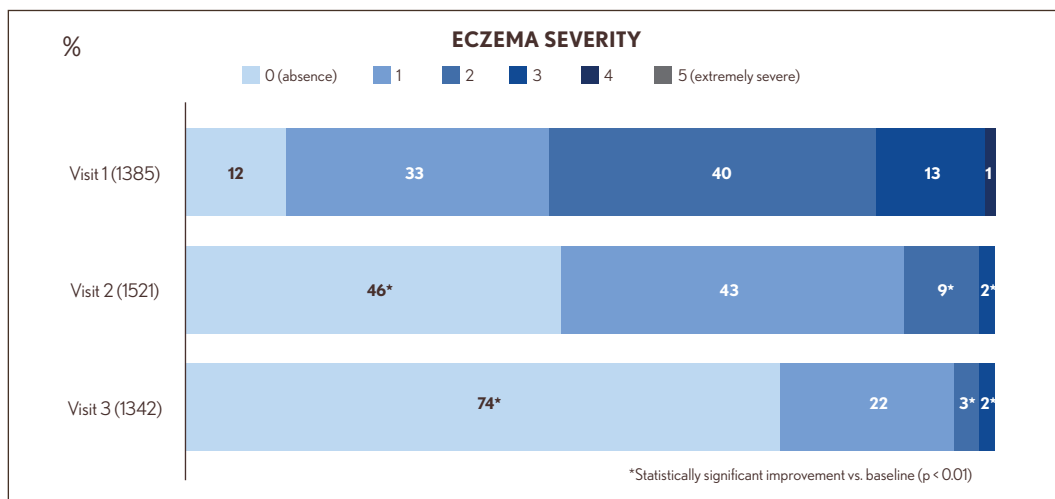
STUDY DESIGN

1,607 patients between the ages of 2 months and 16 years with mild-to-moderate eczema with or without topical steroids/ immunomodulators completed this 8 week observational study. Investigator Global Assessment (IGA), Self-assessment and Quality of Life questionnaires were completed at 4 and 8 weeks.

RESULTS

EFFICACY

Significant improvement in IGA scores (eczema severity) were observed at all time points



78% of patients felt they used less medication at visit 2.

HIGH LEVELS OF SATISFACTION

- 88% of patients indicated they would continue to use the regimen

WELL TOLERATED

- Among 1,607 patients who participated in the observational study, AVEENO® Eczema Therapy Moisturizing Cream and AVEENO® Baby Cleansing Therapy Moisturizing Wash were well tolerated by 98% of patients.

CONCLUSIONS

The results from this observational study with daily use of AVEENO® Eczema Therapy Moisturizing Cream and AVEENO® Baby Cleansing Therapy Moisturizing Wash show IGA improvement in eczema severity at all time points over the course of the study. Consequently, subjects had a high level of satisfaction with the products and felt less need to use medication leading to increased compliance to use of the regimen beyond the study period.

6. COMPARING THE EFFECTIVENESS OF AVEENO® ECZEMA THERAPY MOISTURIZING CREAM AND A LEADING PRESCRIPTION SKIN BARRIER EMULSION IN IMPROVING SKIN MOISTURIZATION AND BARRIER FUNCTION IN MODERATE TO SEVERE DRY SKIN (n=27) Nebus J, Nystrand G, Schmalenberg K, et al. J Am Acad Dermatol. 2011; 64:AB71.

OBJECTIVE

The objective of this study was to measure the effects of AVEENO® Eczema Therapy Moisturizing Cream and a leading prescription skin barrier emulsion in improving the condition of moderate to severely dry skin on the lower leg area over a 7-day treatment period followed by a 2-day regression.

STUDY DESIGN

Twenty seven female subjects between the ages of 18-65 years old, with moderate to severe dry skin on both lower legs participated in this doubled blinded, randomized clinical study.

- Subjects had a 3-5 day washout period prior to the baseline visit.
- Subjects were prohibited from using any product on the lower leg area except the test products and the provided leading prescription skin barrier emulsion.
- The first part of the study involved a single application with evaluations up to the 24 hour time point.
- The second part involved twice daily applications for 1 week immediately followed by a 2 day regression period.
- Clinical grading for Dryness, Scaling and Irritation parameters was completed on days 0, 1, 4, 7 and 9
- Instrumental evaluations for TEWL (Transepidermal Water Loss) were completed on days 0, 1, 4, 7 and 9
- Skicon (Conductance) measurements were completed on days 0, 1, 4, 7 and 9

RESULTS

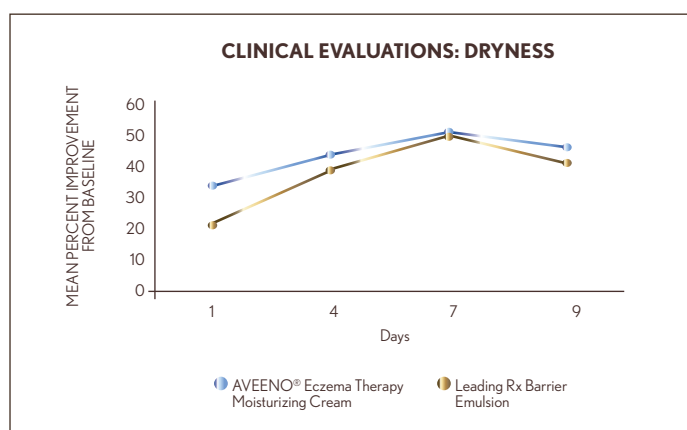
AVEENO® Eczema Therapy Moisturizing Cream demonstrated excellent benefits in alleviating moderate to severe dry skin and was comparable to a leading prescription skin barrier emulsion in improving the skin barrier.¹ Both products were also effective in reducing dryness and scaling as determined by clinical evaluations.

CLINICAL EVALUATIONS

Clinical evaluations of dryness and scaling showed significant improvement in dryness and scaling for both treatment groups at the day 1, 4, 7 and 9 time point.¹

DRYNESS	DAY 1	DAY 4	DAY 7	DAY 9
AVEENO® Eczema Therapy Moisturizing Cream	✓	✓	✓	✓
Leading Rx Barrier Emulsion	✓	✓	✓	✓
SCALING				
AVEENO® Eczema Therapy Moisturizing Cream	✓	✓	✓	✓
Leading Rx Barrier Emulsion	✓	✓	✓	✓

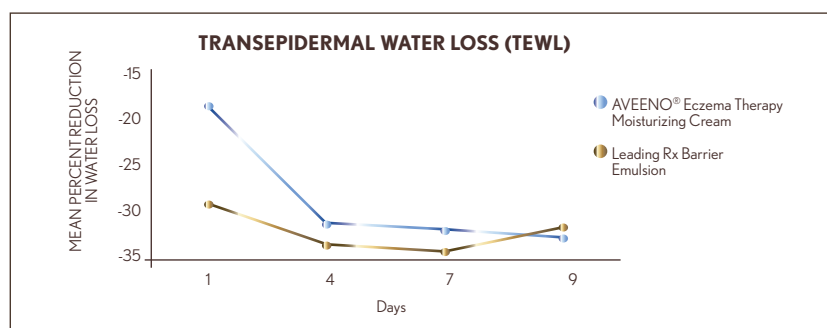
✓ = Significant improvement compared to baseline values.



INSTRUMENTAL ASSESSMENTS

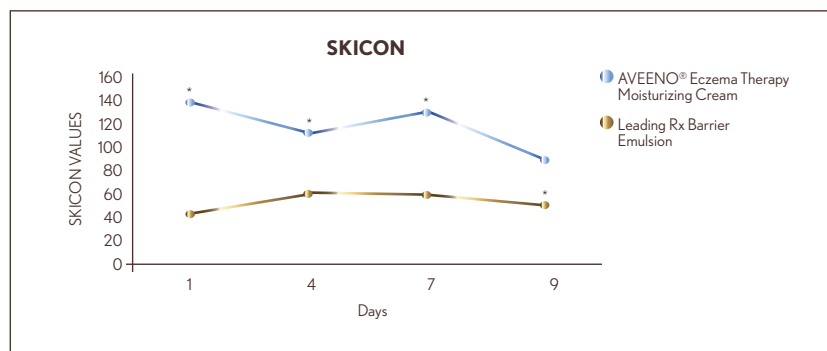
TEWL

A decrease in TEWL values is indicative of an improvement in the skin barrier. For both treatment groups, significant improvements ($p < 0.05$) in TEWL values were measured during all time points (days 1, 4, 7 and 9) of the study when compared to baseline values. There were no significant differences between treatments, both AVEENO® Eczema Therapy Moisturizing Cream and a leading prescription skin barrier emulsion showed improvements in TEWL values on an average of 30% or greater on Days 4, 7 and 9 of the study (see graph below).¹



SKICON MEASUREMENTS

The Skicon instrument measures conductance, higher conductance values are indicative to a higher moisture content of the skin. Both AVEENO® Eczema Therapy Moisturizing Cream and a leading prescription skin barrier emulsion demonstrated significant improvements ($p < 0.05$) in skin surface moisture when compared to baseline values. Sites treated with AVEENO® Eczema Therapy Moisturizing Cream had significantly higher Skicon values when compared to sites treated with a leading Rx barrier emulsion at the Day 1, 4, 7 and 9 (no treatment) time point (see below graph).¹



CONCLUSIONS

In this clinical study, AVEENO® Eczema Therapy Moisturizing Cream demonstrated excellent benefits in alleviating moderate to severe dry skin and was comparable to a leading prescription skin barrier emulsion in improving the skin barrier.¹ Both products were also effective in reducing dryness and scaling as determined by clinical evaluations. In addition, sites treated with AVEENO® Eczema Therapy Moisturizing Cream had significantly higher Skicon values, indicative of surface hydration, on days 1, 4, 7 and 9 when compared to sites treated with a leading prescription skin barrier emulsion. For both treatments, the clinical evaluations of dryness and scaling, TEWL and Skicon measurements were significantly improved, when compared to baseline values, even 2 days after the last treatment (day 9) regression phase of the study.

REFERENCES

1. Clinical study, data on file.

7. A DAILY OAT BASED SKIN CARE REGIMEN FOR ATOPIC SKIN

(n=25) Nebus J, Nystrand G, Fowler J, MD, Wallo W. J Am Acad Dermatol. 2009; 60:AB67.

OBJECTIVE

The objective of this study was to evaluate the tolerance and efficacy of AVEENO® Eczema Therapy Moisturizing Cream and AVEENO® Baby Cleansing Therapy Moisturizing Wash in patients with mild to moderate atopic dermatitis.

STUDY DESIGN

Twenty-five subjects between 12 and 60 years old (approximate mean age 29.8 years) with mild to moderate atopic dermatitis according to the criteria of Hanifin and Rajka (and at least 5% Body Surface Area (BSA) involved) were enrolled into this multi-center, blinded, clinical study. For 8 weeks patients used a daily skin care regimen consisting of twice a day application of AVEENO® Eczema Therapy Moisturizing Cream and once a day use of AVEENO® Baby Cleansing Therapy Moisturizing Wash in the shower or bath. Patients were allowed to use their normal topical medications for their atopic dermatitis. Independent dermatologist evaluations were performed at multiple time points during the study.

- Subjects had to be on a stabilized treatment regimen (topical steroids or prescription topical eczema medications, including flare medications) but were required to stop any current body moisturizers.
- The study was approved by an IRB and informed consent was obtained from all subjects.

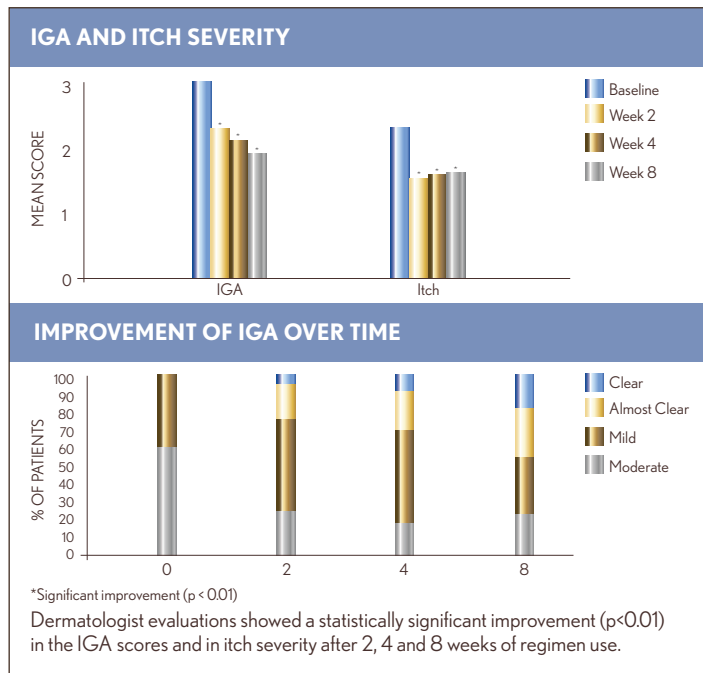
Clinical and subjective evaluations were performed at Weeks 0 (Baseline), 2, 4, and 8. These included:

- Investigators' Global Assessment (IGA) using a 0-5 scale
- Investigator scoring of Eczema Area and Severity Index (EASI) was performed separately for head/neck, trunk, upper limbs and lower limbs. The overall EASI composite score was also calculated
- Moisturization was measured instrumentally on an uninvolved site on the mid-lower leg (Weeks 0, and 8)
- Dermatology Life Quality Index (DLQI) (Weeks 0, 4 and 8) consisted of responses to 10 questions based on skin problems the patient encountered during the previous week. Separate questionnaires were provided for adults (>17 years) and children (12-16 years)
- Subject safety assessments (0-4 scale): itching, burning and stinging
- Final subject assessments based on the efficacy and acceptability of the regimen were completed at the Week 8 visit

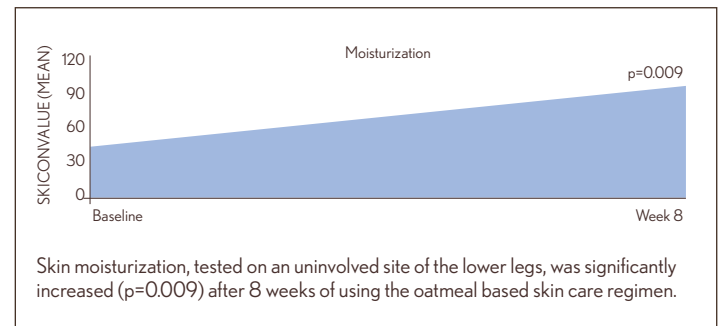
RESULTS

The skin care regimen consisting of AVEENO® Eczema Therapy Moisturizing Cream and AVEENO® Baby Cleansing Therapy Moisturizing Wash was well tolerated in patients with mild to moderate atopic dermatitis. Efficacy results showed a statistically significant improvement in many parameters, including IGA, EASI, itch and moisturization. Burning and stinging, which were mostly absent at baseline, did not change during the study. The regimen was found also to be compatible with various topical eczema medications used by several subjects. These included: triamcinolone (9 subjects), hydrocortisone (4), desonide (2), halobetasol propionate (1), desoximetasone (1), tacrolimus (1), and pimecrolimus (1).

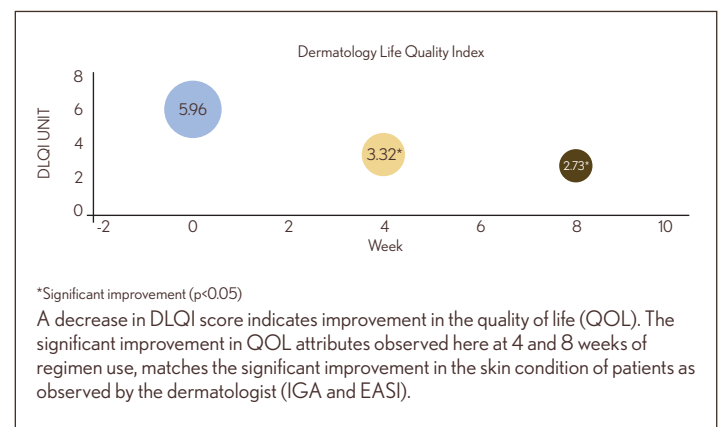
DERMATOLOGIST ASSESSMENT: IGA AND ITCH SEVERITY



SKIN MOISTURIZATION MEASURED BY SKICON



DERMATOLOGY LIFE QUALITY INDEX (DLQI)



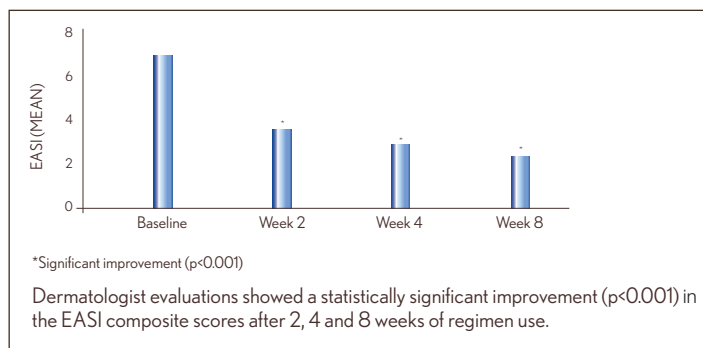
INVESTIGATOR GLOBAL ASSESSMENT

% PATIENTS IN EACH IGA CATEGORY OVERTIME

	0	2	4	8
Severe	-	-	-	-
Moderate	61	24	17	23
Mild	39	52	52	32
Almost Clear	-	19	22	27
Clear	-	5	9	18

Improvement in IGA scores was apparent throughout the study, but especially within the first 2 weeks of treatment.

DERMATOLOGIST ASSESSMENT: EASI COMPOSITE SCORE



FINAL PRODUCT SUBJECT ASSESSMENT

FINAL SELF-ASSESSMENT	% OF PATIENTS AGREEING
Effective in hydrating the skin	83
Gentle and mild to skin	79
Softening and soothing irritated skin	79
Alleviating signs and symptoms of eczema	71
Alleviating itch and skin discomfort	70
Soothing and calming the discomfort of eczema through the night	70

Final self assessments showed that patients liked the regimen finding it soothing, moisturizing and effective in alleviating skin discomfort.

CONCLUSIONS

The study showed that:

- The regimen of AVEENO® Eczema Therapy Moisturizing Cream and AVEENO® Baby Cleansing Therapy Moisturizing Wash was beneficial and well tolerated in subjects with atopic dermatitis.
- The regimen was compatible with the concomitant topical eczema medications used.
- IGA, EASI and itch severity were all significantly improved as early as week-2 of use during this study.
- Dermatology Life Quality Index was significantly improved at 4 and 8 weeks.
- Instrumental evaluation demonstrated that the oat based regimen provided significant skin moisturization.

REFERENCES

1. Kurtz ES, Wallo W. Colloidal oatmeal: history, chemistry and clinical properties. *J Drugs Dermatol*. 2007;6:167-70.
2. Nebus J, Wallo W, Chu M. The effectiveness of an oat-based occlusive cream and oat-based glycerin body wash in the management of atopic dermatitis. *J Am Acad Dermatol*. 2008; 58:AB53.
3. Nebus J, Wallo W. Evaluating the tolerance of an oat-based cream and cleanser in infants and children with atopic dermatitis. *J Am Acad Dermatol*. 2008; 58:AB52.

8. EVALUATING THE TOLERANCE AND SAFETY OF AVEENO® ECZEMA THERAPY MOISTURIZING CREAM AND AVEENO® BABY CLEANSING THERAPY MOISTURIZING WASH IN BABIES AND CHILDREN WITH

ATOPIC DERMATITIS (n=23) Nebus J, Wallo W, Eichenfeld L, MD; Poster presented at the 34th Annual Meeting of the Society of Pediatric Dermatology. July 2008.

OBJECTIVE

The objective of this study was to evaluate the tolerance and safety of AVEENO® Eczema Therapy Moisturizing Cream and AVEENO® Baby Cleansing Therapy Moisturizing Wash in babies and children with atopic dermatitis.

STUDY DESIGN

Twenty-three male or female children between the ages of 2 months to 6 years completed this four-week, monadic study to assess the safety and tolerance of AVEENO® Eczema Therapy Moisturizing Cream and AVEENO® Baby Cleansing Therapy Moisturizing Wash on babies and children with mild to moderate atopic dermatitis.

- To qualify, patients had to have mild to moderate atopic dermatitis according to the criteria of Hanifin and Rajka with at least 5% Body Surface Area (BSA) involved.
- Patients were excluded if they exhibited cutaneous bacterial or fungal infections. Topical eczema treatments already in use were continued. This protocol was approved by an IRB and informed consent was obtained from the patient's parent or legal guardian.
- All patients used AVEENO® Eczema Therapy Moisturizing Cream twice a day and AVEENO® Baby Cleansing Therapy Moisturizing Wash was used for all routine bathing.

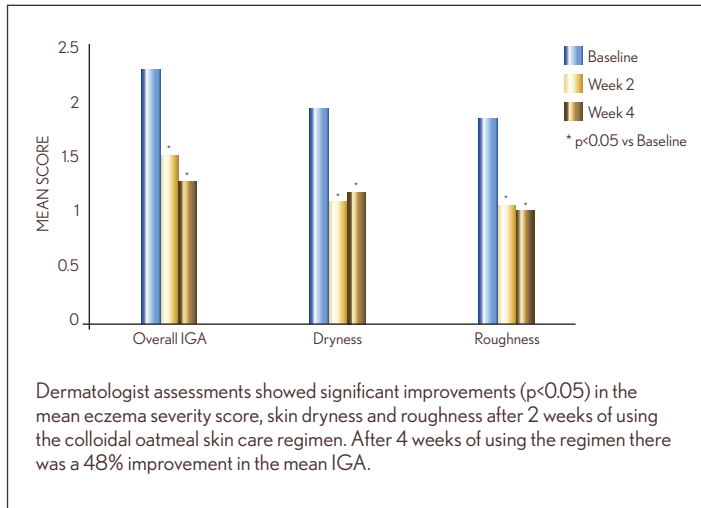
Clinical evaluations were performed at baseline, weeks 2 and 4:

- Dermatologist grading for Investigators Global Assessment (IGA) and other cutaneous and dryness parameters
- Standardized Infant/Child Dermatitis Quality of Life Index completed by child (age dependent) or parent/legal guardian (baseline and week 4)
- Itch assessment utilizing Visual Analog Scoring

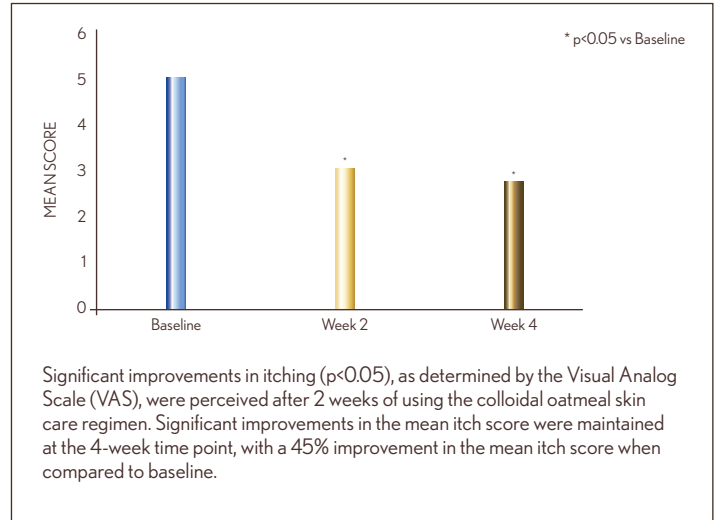
RESULTS

The moisturizing skin care regimen consisting of a colloidal oatmeal cleanser and occlusive cream with ceramides, avenanthramides and panthenol (AVEENO® Baby Cleansing Therapy Moisturizing Wash and AVEENO® Eczema Therapy Moisturizing Cream) was well tolerated by babies/children with mild to moderate atopic dermatitis. There were no significant increases in mean scores for eczema severity, itch or other cutaneous irritation parameters¹ Twenty-five patients were enrolled and twenty-three completed the study. No serious skin reactions were reported.

DERMATOLOGIST ASSESSMENTS: IGA AND DRY SKIN PARAMETERS



MEAN ITCH SCORE (VISUAL ANALOG SCALE)

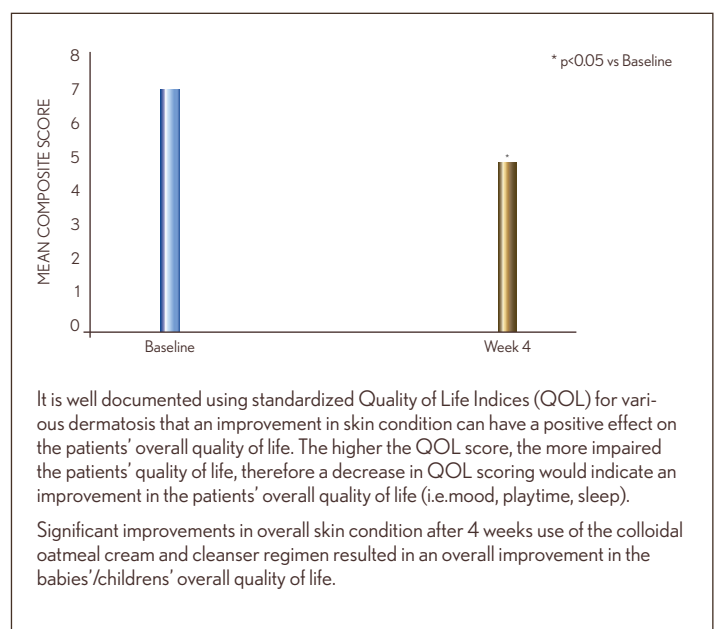


INVESTIGATOR GLOBAL ASSESSMENT

	Baseline	Week
Severe	-	-
Moderate	73%	4%
Mild	27%	36%
Almost Clear	-	43%
Clear	-	17%

Improvements in the severity of eczema, as determined by specific IGA categories, were observed in patients that used the colloidal oatmeal regimen for 4 weeks. At the baseline visit, 73% of the population exhibited a moderate score for eczema severity, after using the regimen for 4 weeks only 4% exhibited a moderate eczema severity score.

QUALITY OF LIFE: BABIES/CHILDREN



CONCLUSIONS

The regimen of AVEENO® Eczema Therapy Moisturizing Cream and AVEENO® Baby Cleansing Therapy Moisturizing Wash was well tolerated and beneficial to babies and children with mild to moderate atopic dermatitis.

- Dermatologist evaluations showed significant improvements ($p < 0.05$) in the Investigators Global Assessment (IGA) of Eczema Severity after 2 and 4 weeks of use. Improvements in IGA severity scoring were observed with a high percentage of patients exhibiting moderate eczema upon study enrollment and the majority of patients, after 4 weeks of regimen use, exhibiting mild/almost clear IGA scores.
- Dermatologist evaluations showed significant improvements ($p < 0.05$) in overall dryness and roughness after 2 and 4 weeks of use.
- Significant improvements ($p < 0.05$) in itching were perceived after 2 and 4 weeks using the regimen.
- Improvements in skin condition resulted in overall improvements in the Quality of Life after 4 weeks of using the regimen as determined by standardized Baby/Child Quality of Life Indices for Dermatitis.

9. EVALUATING THE SAFETY AND TOLERANCE OF AVEENO® ECZEMA THERAPY MOISTURIZING CREAM AND AVEENO® BABY CLEANSING THERAPY MOISTURIZING WASH IN PATIENTS WITH ATOPIC DERMATITIS (n=21) Nebus J, Wallo W, Fowler J, MD; J Am Acad Dermatol. 2007; 56:AB71.

OBJECTIVE

The objective of this study was to evaluate the tolerance and efficacy of AVEENO® Eczema Therapy Moisturizing Cream and AVEENO® Baby Cleansing Therapy Moisturizing Wash in patients with mild to moderate atopic dermatitis.

STUDY DESIGN

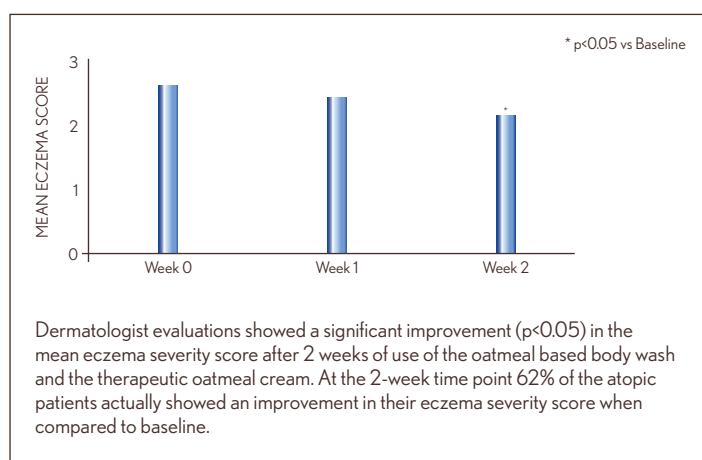
Twenty-one healthy patients between the ages of 15 and 60 with mild to moderate atopic dermatitis (according to the criteria of Hanifin and Rajka) and at least 5% body surface area of involvement were entered into the study.

- Patients with severe atopy, those with a history of recurrent cutaneous infections, or those with known allergies to ingredients in the test products study were excluded from the study.
- This protocol was approved by an IRB and informed consent was obtained from all patients.
- Subjects were allowed to continue using their OTC or prescription topical treatments for atopy.
- Patients used AVEENO® Baby Cleansing Therapy Moisturizing Wash once a day for showering or bathing. They applied AVEENO® Eczema Therapy Moisturizing Cream to their arms, legs, hands and torso twice a day for the duration of the two-week study.
- Patients were allowed to apply the cream more often if necessary, and were required to record usage in their diary.
- Investigator evaluations were performed at Day 0, 7, and 14 with final self-assessments at Day 14

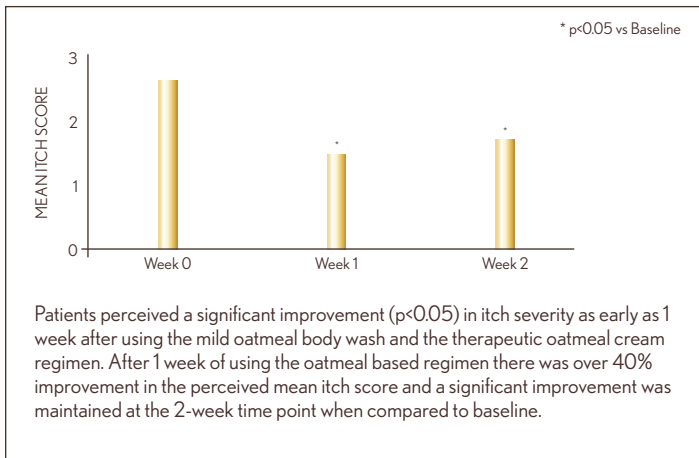
RESULTS

The regimen of AVEENO® Eczema Therapy Moisturizing Cream and AVEENO® Baby Cleansing Therapy Moisturizing Wash was well-tolerated by patients with mild to moderate atopic dermatitis. There were no significant increases in the mean scores for eczema severity, itch, or any of the clinical safety parameters observed during the 2-week study period.¹

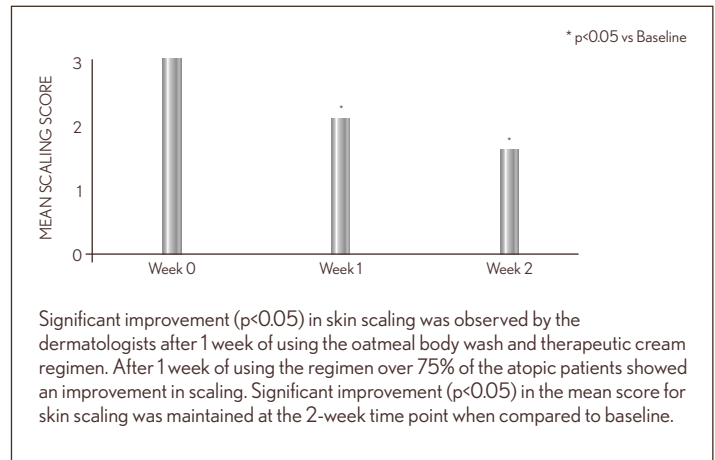
DERMATOLOGIST ASSESSMENTS: ECZEMA SEVERITY



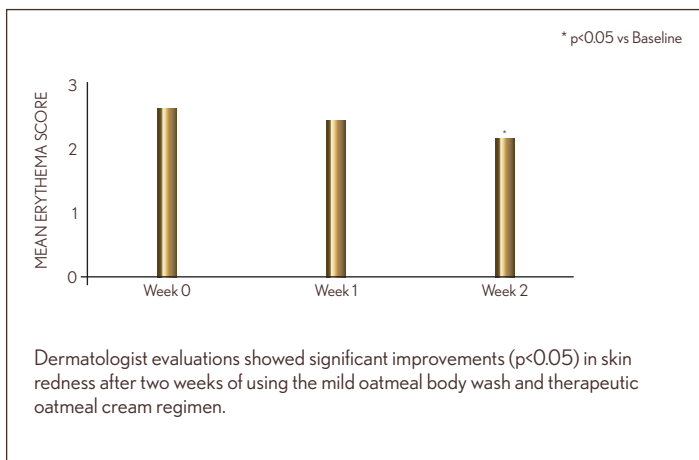
DERMATOLOGIST ASSESSMENTS: ITCH SEVERITY



DERMATOLOGIST ASSESSMENTS: SCALING



DERMATOLOGIST ASSESSMENTS: ERYTHEMA



FINAL SELF ASSESSMENTS

PERCENT OF PATIENTS AGREEING

DRYNESS

Gentle and mild to skin	100
Effective in providing moisturization	100
Liked the regimen	75
Felt their skin was in an overall better condition	66

CREAM

Left skin feeling soft and smooth	100
Provides the right amount of moisturization	90
Was effective in relieving their itchy skin	80

CLEANSER

Gentle to the skin	100
Left skin feeling moisturized after use	100
Provides just the right amount of lather	80

CONCLUSIONS

This regimen of AVEENO® Eczema Therapy Moisturizing Cream and AVEENO® Baby Cleansing Therapy Moisturizing Wash was well-tolerated and beneficial to patients with mild to moderate atopic dermatitis.

- Dermatologist evaluations showed a significant improvement in the mean eczema score after 2 weeks of use.
- Dermatologist evaluations showed significant improvements in skin scaling and erythema.
- Atopic patients perceived significant improvements in itch as early as week 1 after starting use of the regimen.
- Instrumental assessments proved that the cream provided 24-hour moisturization to the skin.

