

#### **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 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. ASSESSMENT OF AVEENO® ECZEMA THERAPY
MOISTURIZING CREAM THROUGH A
MULTI-CENTRIC CLINICAL STUDY ON
INFANTS, CHILDREN AND ADULTS WITH
ATOPIC DERMATITIS

ASSESSMENT OF AVEENO® ECZEMA THERAPY MOISTURIZING CREAM THROUGH A MULTI-CENTRIC CLINICAL STUDY ON INFANTS, CHILDREN AND ADULTS WITH ATOPIC DERMATITIS (n=71) 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

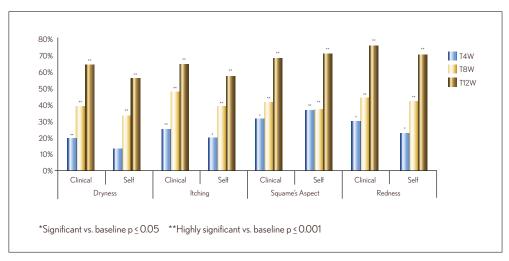
99 patients between the ages of six months and adulthood with mild-to-moderate atopic dermatitis were enrolled in this open 12 week multi-centric study in Greece, Portugal and Italy. 71 patients completed the study. Evaluations included SCORAD, Clinical grading, instrumentation, Self-assessment and Quality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

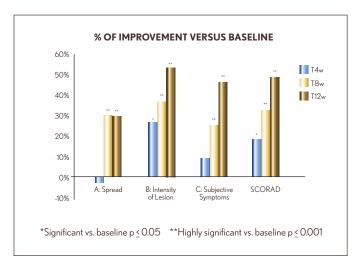
#### **RESULTS**

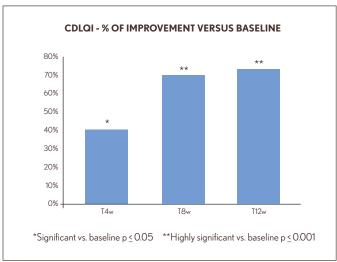
Use of AVEENO® Eczema Therapy Moisturizing Cream resulted in significant improvement in skin conditions parameters. At week 12:

- 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<sup>1</sup>

#### **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.



### 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

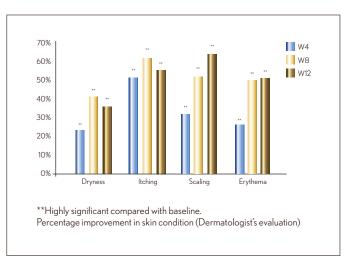
75 patients between the ages of 2 and 65 years old with mild-to-moderate atopic eczema with or without topical steroids/immunomodulators/antihistamines completed this 12 week open study carried out in Brazil (Campinas, São Paulo State). Evaluations included SCORAD, Clinical grading instrumentation, Self-assessment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

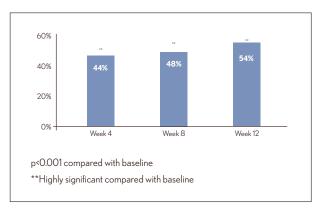
#### PERCENTAGE IMPROVEMENT IN CLINICAL PARAMETERS OF ATOPIC SIGNS CLINICAL GRADING - COMPARED WITH BASELINE VISIT



#### **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.

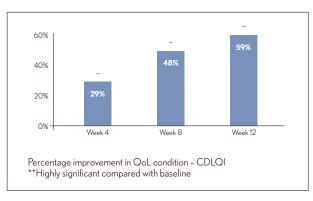
#### PERCENTAGE IMPROVEMENT IN SCORAD



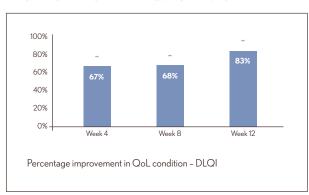
#### QUALITY OF LIFE

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



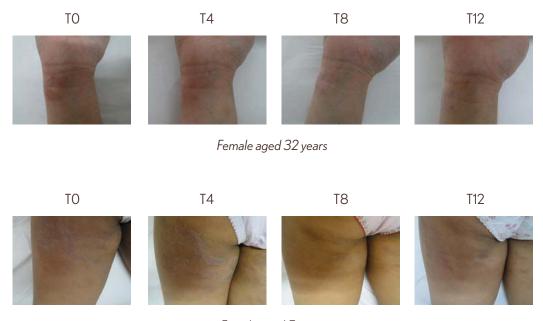
#### PERCENTAGE IMPROVEMENT IN QoL FOR ADULTS



#### **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

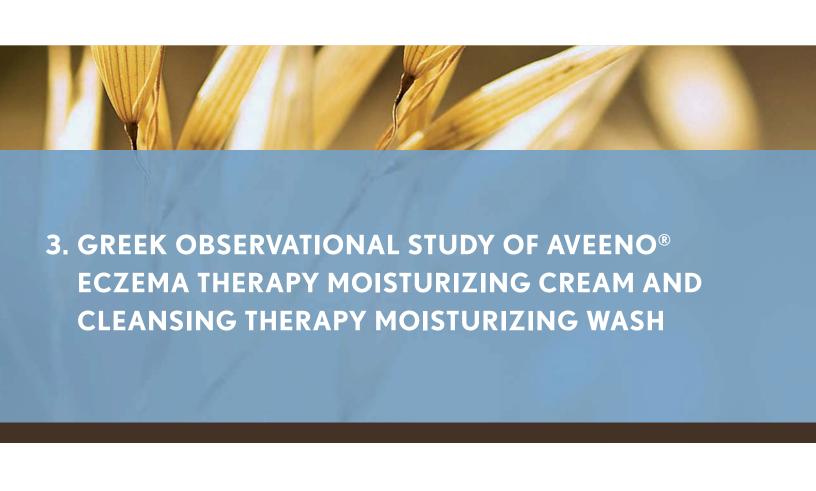


Female aged 5 years

#### **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.



## 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.

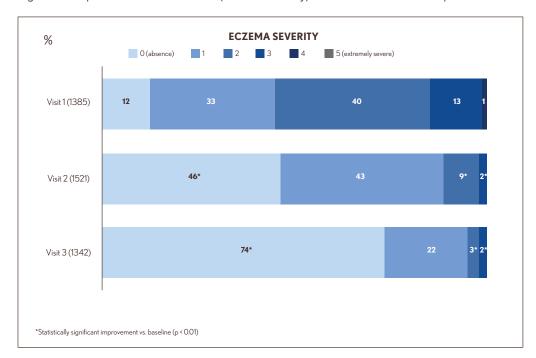
#### STUDY DESIGN

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 times 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.

4. COMPARING THE EFFECTIVENESS OF AVEENO®
ECZEMA THERAPY MOISTURIZING CREAM AND A
LEADING PRESCRIPTION SKIN BARRIER EMULSION IN
IMPROVING THE SKIN MOISTURIZATION AND BARRIER
FUNCTION IN MODERATE TO SEVERE DRY SKIN

# 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 PURPOSE® Gentle Skin Cleanser.
- 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

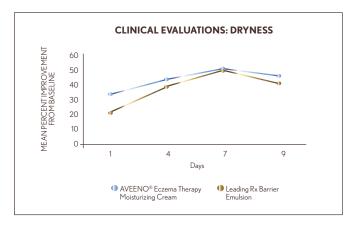
#### **RESULTS**

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.<sup>1</sup>

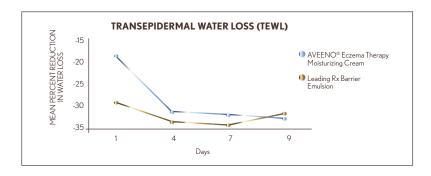
DRYNESS	DAY 1	DAY 4	DAY 7	DAY 9
AVEENO® Eczema Therapy Moisturizing Cream	√	√	<b>√</b>	<b>√</b>
Leading Rx Barrier Emulsion	<b>√</b>	<b>√</b>	✓	√
Scaling				
Mild Oatmeal Based Moisturizing Cream	<b>√</b>	√	√	<b>√</b>
Leading Rx Barrier Emulsion	✓	√	<b>√</b>	√



#### **INSTRUMENTAL ASSESSMENTS**

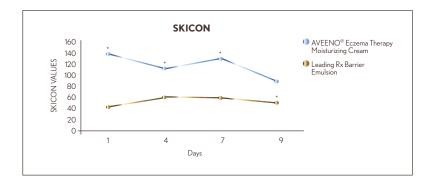
#### **TEWL**

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).<sup>1</sup>



#### 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).



#### **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.



#### 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.

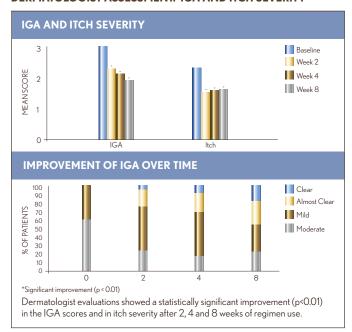
Clinical and subjective evaluations were performed at Weeks O (Baseline), 2, 4, and 8. These included:

- 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 O, 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**

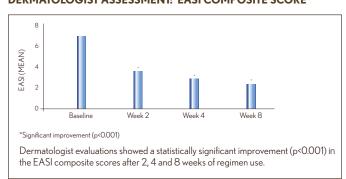


#### **INVESTIGATOR GLOBAL ASSESSMENT**

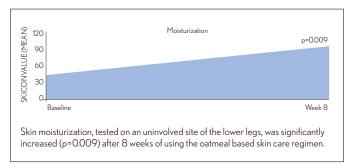
within the first 2 weeks of treatment.

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

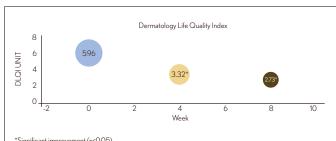
#### **DERMATOLOGIST ASSESSMENT: EASI COMPOSITE SCORE**



#### SKIN MOISTURIZATION MEASURED BY SKICON



#### **DERMATOLOGY LIFE QUALITY INDEX (DLQI)**



\*Significant improvement (p<0.05)

A decrease in DLQI score indicates improvement in the quality of life (QOL). The significant improvement in QOL attributes observed here at 4 and 8 weeks of regimen use, matches the significant improvement in the skin condition of patients as observed by the dermatologist (IGA and EASI).

#### **FINAL PRODUCT SUBJECT ASSESSMENT**

FINAL SELF-ASSESSMENT	% OF PATIENTS AG	REEING
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 ec	zema through the night	70
Final self assessments showed that patients moisturizing and effective in alleviating skin	liked the regimen finding it so	oothing

#### **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.

6. 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

### 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.

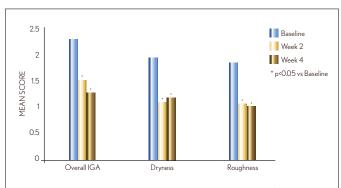
Clinical evaluations were performed at baseline, weeks 2 and 4:

- 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**

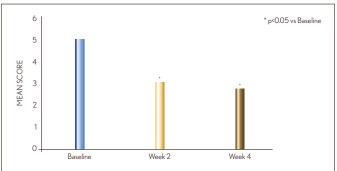
The moisturizing skin care regimen consisting of a colloidal oatmeal cleanser and occlusive cream with ceramides, avenanthramides and panthenol (AVEENO® Baby Cleansing Therapy Moisturizing Wash and AVEENO® Eczema Therapy Moisturizing Cream) was well tolerated by babies/children with mild to moderate 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**



Dermatologist assessments showed significant improvements (p<0.05) in the mean eczema severity score, skin dryness and roughness after 2 weeks of using the colloidal oatmeal skin care regimen. After 4 weeks of using the regimen there was a 48% improvement in the mean IGA.

#### MEAN ITCH SCORE (VISUAL ANALOG SCALE)



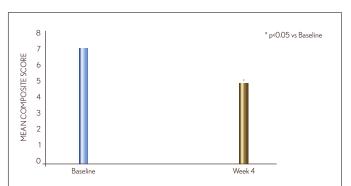
Significant improvements in itching (p<0.05), as determined by the Visual Analog Scale (VAS), were perceived after 2 weeks of using the colloidal oatmeal skin care regimen. Significant improvements in the mean itch score were maintained at the 4-week time point, with a 45% improvement in the mean itch score when compared to baseline.

#### **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**



It is well documented using standardized Quality of Life Indices (QOL) for various dermatosis that an improvement in skin condition can have a positive effect on the patients' overall quality of life. The higher the QOL score, the more impaired the patients' quality of life, therefore a decrease in QOL scoring would indicate an improvement in the patients' overall quality of life (i.e.mood, playtime, sleep).

Significant improvements in overall skin condition after 4 weeks use of the colloidal oatmeal cream and cleanser regimen resulted in an overall improvement in the babies '/childrens' overall quality of life.

#### **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.

7. EVALUATING THE SAFETY AND TOLERANCE OF AVEENO® ECZEMA THERAPY MOISTURIZING CREAM AND AVEENO® BABY CLEANSING THERAPY MOISTURIZING WASH IN PATIENTS WITH ATOPIC DERMATITIS

## 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

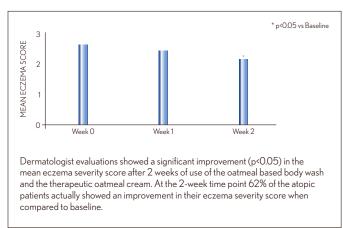
Twenty-one healthy patients between the ages of 15 and 60 with mild to moderate atopic dermatitis (according to the criteria of Hanifin and Rajka) and at least 5% body surface area of involvement were entered into the study.

- 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

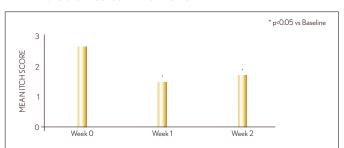
#### RESULTS

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**

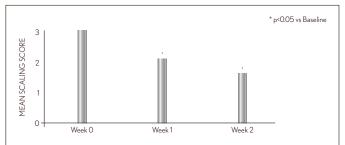


#### **DERMATOLOGIST ASSESSMENTS: ITCH SEVERITY**



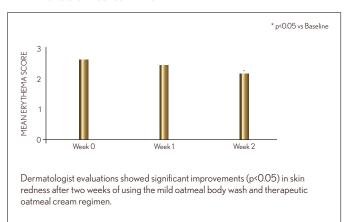
Patients perceived a significant improvement (p<0.05) in itch severity as early as 1 week after using the mild oatmeal body wash and the therapeutic oatmeal cream regimen. After 1 week of using the oatmeal based regimen there was over 40% improvement in the perceived mean itch score and a significant improvement was maintained at the 2-week time point when compared to baseline.

#### **DERMATOLOGIST ASSESSMENTS: SCALING**



Significant improvement (p<0.05) in skin scaling was observed by the dermatologists after 1 week of using the oatmeal body wash and therapeutic cream regimen. After 1 week of using the regimen over 75% of the atopic patients showed an improvement in scaling. Significant improvement (p<0.05) in the mean score for skin scaling was maintained at the 2-week time point when compared to baseline.

#### **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 conditi	on 66
CREAM Left skin feeling soft and smooth	100
Provides the right amount of moisturization	90
Was effective in relieving their itchy skin  CLEANSER	80
Gentle to the skin	100
Left skin feeling moisturized after use	100
_	

#### **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.

NOTES	

