

CLINICAL BENEFITS OF

Colloidal Oatmea

FORMULATION MATTERS

Dry skin affects nearly everyone at some point in their lifetime.

Many emollients are available in products designed to soothe and relieve itchy, dry skin. However, few controlled experiments have been published comparing the efficacy of the active versus the vehicle used to deliver the products to the skin.

Pivotal Study

A Randomized Controlled Clinical Study to Evaluate the Effectiveness of an Active Moisturizing Lotion with Colloidal Oatmeal Skin Protectant Versus Its Vehicle for the Relief of Xerosis¹

Clinical study to evaluate the effectiveness of an AVEENO® Colloidal Oatmeal Lotion versus its vehicle for the relief of xerosis as published in Journal of Drugs in Dermatology 2014

Purpose

Objectively compare the efficacy of a commercially available moisturizing product against its vehicle for relief of skin dryness in a randomized, controlled clinical study.

Key Emollients and Skin Conditioners in products tested:

Colloidal Oatmeal Lotion : Oat Flour, Oat Extract, Oat Oil, Dimethicone, Water, Glycerin, Petrolatum, Shea Butter

Vehicle: Dimethicone, Water, Glycerin, Petrolatum, Shea Butter

Design



18-70 years old **3** week study, 1 week regression

Double-blinded, split leg, controlled study where patients used both products.

Instrumental measurements of hydration (Corneometer, SkiCon), imaging, clinical and patient assessments were conducted at baseline, after 21 days of treatment and after a 1-week regression period without treatment.

Results



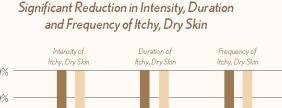
Study showed significantly greater efficacy of AVEENO® Colloidal Oatmeal Lotion versus its vehicle

Clinical grading showed AVEENO® Colloidal Oatmeal Lotion had significantly greater improvements in scaling, overall dryness, and intensity, duration and frequency of itch and significantly better hydration as measured by the Corneometer and Skicon at 21 and again at 28 days (after the 1-week regression).

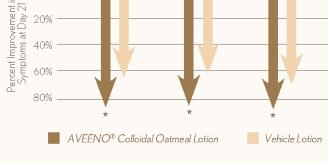
| Clinical Assessment | AVEENO® Colloidal Oatmeal Lotion (N=30) | Vehicle Lotion (Control, N=30) |
|-------------------------|--|-----------------------------------|
| Overall dryness* (mean) | -2.22 | -1.87 |
| Scaling (mean)** | -4.67 | -4.13 |

^{*}mean score of all subjects; score on a 0-9 scale **mean score of all subjects; score on a 0-3 scale

Change in Skin Hydration Measurements:



CLINICAL GRADING:



INSTRUMENTAL MEASUREMENTS:

Significantly Better Moisturization,
Maintained 7 Days After Discontinuation of Use

Top 2 Box Score

Hydration Measured by Cornecmeter

55

Regression Period

45

40

35

Baseline

Day 21

Day 28

AVEENO® Colloidal Oatmeal Lotion

Vehicle Lotion

*Significant improvement (p<0.05) with the AVEENO® Colloidal Oatmeal Lotion when compared to vehicle after 21 days of treatment



This robust, controlled clinical study shows the benefits of colloidal oatmeal in significantly improving scaling, dryness and itch in patients with moderate to severe xerosis.

REFERENCES

. Kalaaji AN, Wallo W. A randomized controlled clinical study to evaluate the effectiveness of an active moisturizing lotion with colloidal oatmeal skin protectant versus its vehicle for the relief of xerosis. J Drugs Dermatol. 2014 Oct;13(10):1265–8. PMID: 25607563.