

A 14-Day, Single-Blind, Controlled Study to Assess the Qualitative Improvement in Skin Moisturization and Desquamation of 15% Lactic Acid Moisturizer with Ceramides (LAMC) Treatment in Healthy Female Subjects

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SYNOPSIS

- Traditional moisturizers with emollients (dimethicone, cetyl alcohol) improve skin appearance by smoothing down dry scaly skin to temporarily improve skin appearance. The dry scaly skin ultimately must desquamate for overall healthy skin.
- Topical application of ingredients, such as alpha-hydroxy acids, can facilitate the natural skin desquamation process. Lactic Acid Moisturizer with Ceramides (LAMC) contains ceramides, humectants and lactic acid that work in combination to moisturize dry skin and induce desquamation.

OBJECTIVES

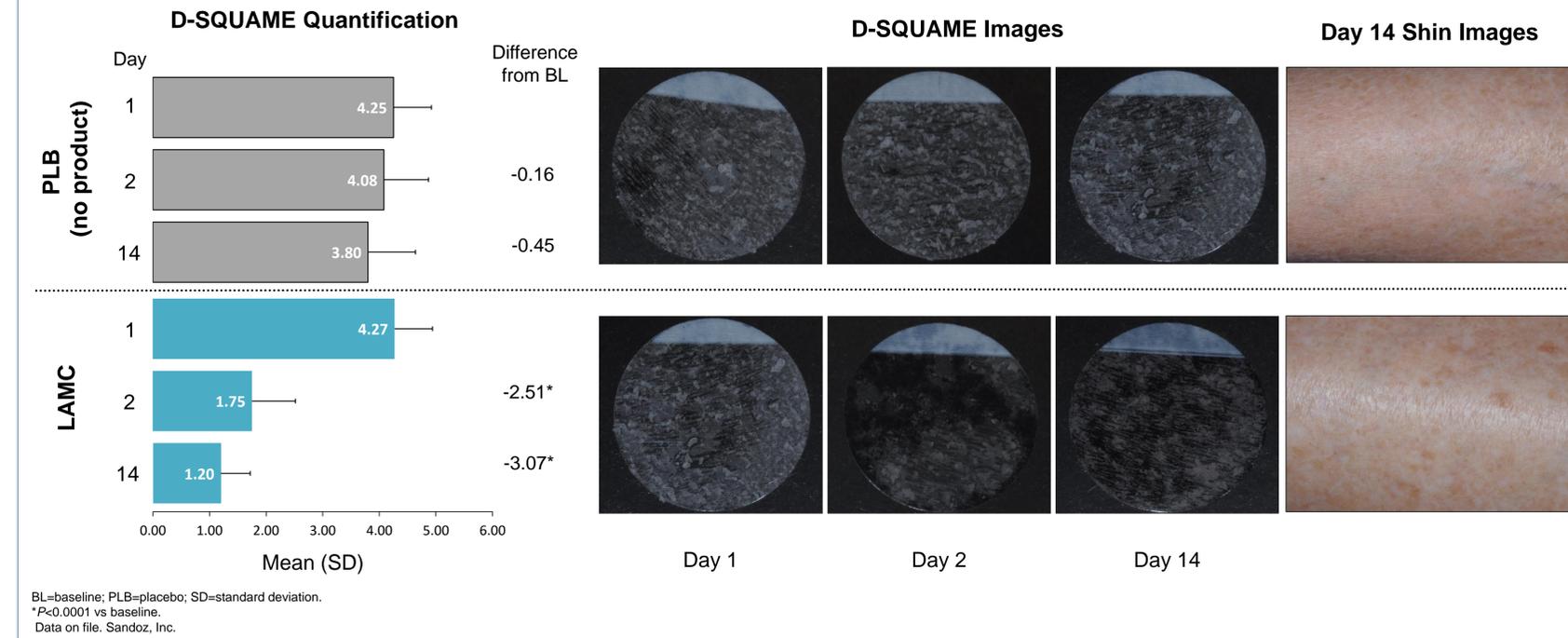
- To investigate if AmLactin® Rapid Relief Restoring Lotion + Ceramides (15% LAMC) improves the skin through moisturization and desquamation.
- To assess safety by the evaluation of any adverse events reported during the study.

METHODS

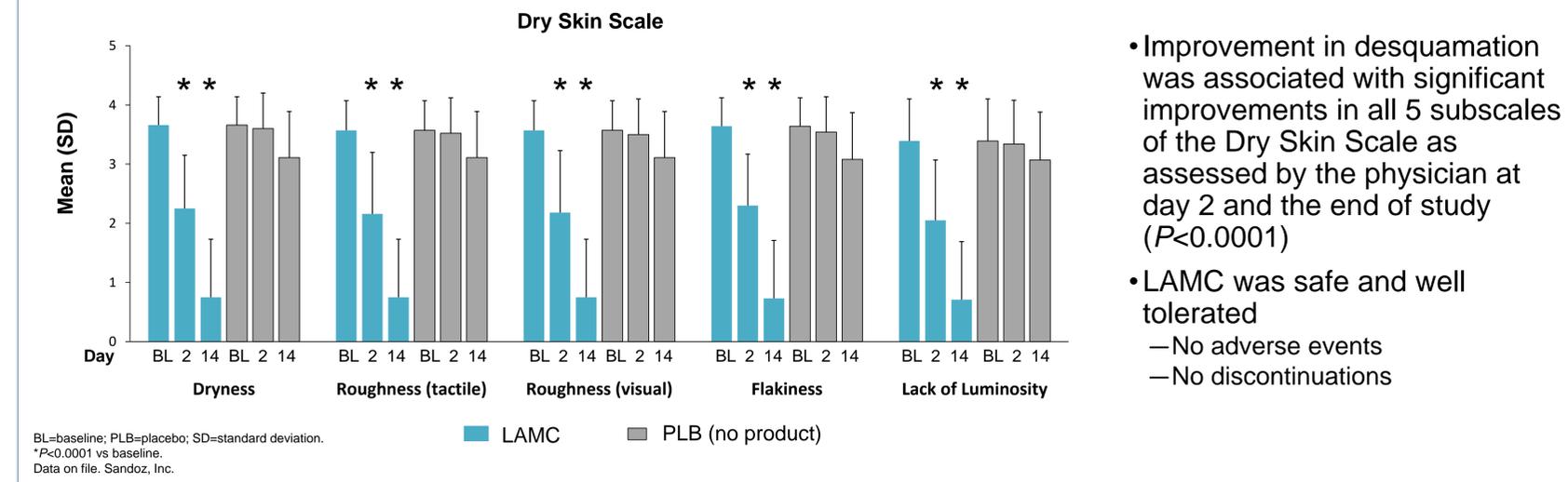
- This was a randomized, single-center, controlled, evaluator-blinded, within-subject comparison study of LAMC versus no treatment in healthy female subjects where subjects served as their own control.
- Fifty-six female subjects 50+ year of age with dry rough skin on the anterior shins (defined as Grade 3-4 on the dermatologist evaluation of the skin; Dry Skin Scale) were enrolled and treated.
- All subjects had a template-located target site identified on both anterior shins for the purpose of determining the moisturization and desquamation potential.
- The study product was applied to the randomized leg twice daily for 14 days.
- Evaluation of moisturization and desquamation potential were assessed clinically using sticky tape corneocyte counts (D-SQUAME®) as well as dermatologist evaluation (skin dryness, skin texture/roughness (tactile), skin texture/roughness (visual), desquamation/flakiness, and luminosity/radiance) of the skin at Baseline, Day 2 and Day 14.
- Additionally, photography of the D-SQUAME® discs and subjects' shins were captured Day 1,2 and 14

RESULTS

LAMC Provided Significant Improvement in Moisturization and Desquamation



LAMC Provided Significant Improvement in Moisturization and Desquamation by Physician Assessment on the Dry Skin Scale



RESULTS

- LAMC demonstrated clinically and statistically significant improvement to no treatment in enhanced moisturization and desquamation via D-SQUAMEs at both Day 2 and Day 14 (-2.51 and -3.07 on a 5-point scale at p<0.0001, respectively).
- Treatment success assessed by the investigator (via the Dry Skin Scale) demonstrated statistical significance with LAMC, with the majority of p values being <0.0001.
- LAMC was well tolerated with no reported adverse events over the duration of the study.

CONCLUSIONS

- LAMC provided a statistically significant and clinically meaningful improvement in moisturization and desquamation as evidenced by D-SQUAME®, Dry Skin Scale, and Subject Self-Assessments in the population studied.
- Additionally, the product appeared to be safe and well tolerated.

REFERENCES

- Black D, Boyer J Lagarde JM. Int J of Cosmetic Sci, 2006;28, 35-44

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DISCLOSURES

- This Study was funded by Sandoz, Inc., Princeton, NJ
- Hall, Munsick employees of Sandoz Inc.

AmLactin® Rapid Relief is a registered trademark of Sandoz Inc.