



AESTHETIC AND COSMETIC DERMATOLOGY (LASERS SEPARATE CATEGORY)

## **THE RAPID, OVER-TIME AND SUSTAINED EFFICACY OF A CERAMIDE-CONTAINING BODY CREAM ON WOMEN WITH DRY, ITCHY SKIN: RESULTS FROM A RANDOMIZED, INVESTIGATOR-BLINDED, SPLIT-LEG CLINICAL STUDY**

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**Objective:** The purpose of this clinical study was to evaluate the rapid, over-time and sustained efficacy of a ceramide-containing body cream used twice daily versus an untreated control in women with dry, itchy skin. Subjects were randomized in a split-leg design and monitored over the course of 4 weeks and again after 48-hours of discontinued product usage (regression).

**Materials and Methods:** This clinical study included 50 women, ages 30-65 with moderate skin dryness, flakiness, roughness, dullness and erythema as assessed by a dermatologist and with self-perceived mild to moderate itchiness. Clinical efficacy was evaluated by expert grading and self-assessment questionnaires at baseline, post-application, day 3, week 4 and after 48-hours regression. Bioinstrumental measurements were performed at each time point except post-application. Additionally, 30 subjects were randomly selected for tape stripping at baseline, week 4 and the 48-hour regression study visit for surface skin lipid analyses.

Objective and subjective tolerance assessments were performed at each study visit. Both the treated and untreated leg were evaluated for all clinical assessments.

**Results:** Statistically significant improvements were observed in all expert graded skin attributes at each time point for the treated leg compared to the untreated leg, with the exception of erythema at the post-application time point. Subject self-assessment of itchiness for the treated leg was significantly improved at the post-application, day 3 and week 4 visits compared to the untreated leg. The treated leg showed a statistically significant improvement in hydration at each time point compared to the untreated leg. Skin lipid analyses showed a statistically significant increase in the total ceramides, cholesterol





and free fatty acid content in the skin surface of the treated leg compared to the untreated leg at week 4. Global tolerance and self-assessment evaluations showed the cream was well tolerated and well perceived by the study panel.

