

CALLEX® EXFOLIATING DRY HEEL OINTMENT

Four week use study to evaluate product efficacy for exfoliating, softening and moisturizing dry feet and 30-day Repeat Insult Patch Test.

EFFICACY STUDY SUMMARY

Conducted by Consumer Products Testing Co.,
Fairfield, NJ. Protocol: XPHH01-003, 2004.

Objective:

To determine the potential of CALLEX OINTMENT to exfoliate, soften and moisturize rough, dry, cracked and flaking skin on all areas of the foot in two and four weeks of twice daily use.

Methodology:

Twenty-eight qualified males and females, ranging in age from 30 to 65 years, were selected for this study. Prior to acceptance, the soles and heels of both feet were visually examined by a registered nurse to assess the degree of rough skin, dryness, flaking and cracking. Feet were scored on each parameter and photographed. Subjects with a score of moderate (2) to severe (4) qualified for the study. After fifteen days and four weeks of twice daily product usage, subjects returned for photographs of the treatment sites. A dermal examination, as previously described, was repeated after four weeks. Subjects were required to maintain daily dairies.

Results:

A dependent t-test was utilized to determine if there were statistically significant differences between the baseline and post-treatment evaluation scores.

Scoring Evaluation Scale:

0 – none; 1 – mild; 2 – moderate; 3 – marked; 4 – severe

Summary:

Under the conditions of this study CALLEX OINTMENT significantly reduced the severity of dry, flaking and cracking skin on soles and heels.

REPEATED INSULT PATCH TEST:

A Repeated Insult Patch Test (RIPT) was also conducted and did not indicate a potential for dermal irritation or allergic contact sensitization.

CALLEX OINTMENT - BASELINE VS. 4 WEEKS OF USE

Mean scores for:	<u>Baseline</u> Left/ Right	<u>After 4 weeks</u> Left/ Right
Dryness	2.3 / 2.3	↓ 0.8/ 0.8 ↓
Cracking	2.0 / 1.8	↓ 0.9 / 0.8 ↓

↓ Highly significant