CALLEX® OINTMENT CLINICAL STUDIES

Four week studies to evaluate product efficacy for softening, exfoliating and moisturizing the foot and in-use safety in an insulin-dependent diabetic population

Objective:

To determine the potential of a topical product to soften, exfoliate and moisturize harden, dry, thickened or flaking skin on dry, cracked heels, feet and cuticles.

Participants:

Twenty-eight (28) qualified males and females, ranging in age from 30 to 65 years, were selected for this study.

Methodology:

Prior to acceptance, each subject received a complete dermatological examination by a Registered Nurse for acceptance into the study. The soles and the heels of both feet and cuticles of all fingernails were examined visually to assess the degree of hardened skin, dryness, flaking and cracking. Data was recorded on a clinical record form and all subjects hands and feet were photographed to record the appearance of hardened skin, flaking, dryness or cracking on the sole or heel.

Evaluation Key:

0	=	None
+	=	Barely Perceptible
1	=	Mild
2	=	Moderate
3	=	Marked
4	=	Severe

Subjects must have presented with a score of moderate (2) to severe (4) to qualify for the study. After fifteen (15) days and four (4) weeks of product usage, subjects returned to the Laboratory and photographs were taken of the treatment sites, as previously described. A dermal examination, as previously described, was repeated after four (4) weeks of product use.

Statistical Analysis:

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

Summary:

Under the conditions of this study, the test material (CALLEX OINTMENT) significantly reduced the severity of several clinical parameters associated with hardened or thickened skin, dry or flaking skin, and cracking on soles or heels.

Four Week In-Use Safety Study in an Insulin-Dependent Diabetic Population

Objective:

To determine if repeated use of a foot ointment in an insulin-dependent diabetic population will elicit adverse reactions.

Participants:

Twenty-six (26) qualified males and females, ranging in age from 23 to 64 years, were selected for this study.

Methodology:

Prior to acceptance, each subject received a complete dermatological examination by a Registered Nurse. Observations of the soles and the heels of both feet for dryness, edema and erythema were recorded on clinical record forms. Subjects exhibiting a score of moderate (2) or greater for any clinical parameter were excluded from the study.

Methodology Evaluation Key:

0	=	None
+	=	Barely Perceptible
1	=	Mild
2	=	Moderate
3	=	Marked
4	=	Severe

After completion of the dermatological examination, acceptable candidates received the test product, a daily diary and written instructions for use.

A dermal examination, as previously described, was repeated after four (4) weeks of product use.

Summary:

Under the conditions of the study, test material, CALLEX OINTMENT, did not elicit any adverse reactions on the insulin-dependent diabetics in this study under normal use conditions.

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

Studies conducted in 2003 by Consumer Products Testing Co., Fairfield, NJ.