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An open-label study of the safety and efficacy of sertaconazole nitrate in the treatment of seborrheic dermatitis.

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Source

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Abstract

OBJECTIVES:

To demonstrate the efficacy and evaluate the safety of sertaconazole nitrate cream 2% in the treatment of seborrheic dermatitis (SD).

DESIGN:

Single-center, open-label study.

SETTING:

One academic medical center.

PARTICIPANTS:

Twenty adult male and female subjects aged 22 to 85 years (average, 56 years) with mild-to-severe seborrheic dermatitis of the face. Measurements: The primary efficacy evaluation was the proportion of subjects with a score of 0 or 1 at the end of treatment (week 4) on the Investigator's Static Global Assessment scale. Secondary end points included percent change from baseline to week 4 in sum individual scores of erythema, scaling, induration, and pruritus at a preselected target lesion. Other end points included change in scores on Subject's Global Assessment scale and the Dermatology Life Quality Index.

RESULTS:

Success on the primary end point was achieved by 10 of 17 evaluable subjects (58.8%). Improvements in Investigator's Static Global Assessment score from baseline were statistically significant at each week. Significant improvements were also demonstrated in erythema, scaling, induration, and pruritus at week 4 compared to baseline. Improvement in Subject's Global Assessment scores compared to baseline were significant only at week 1 (P=0.031). Change in total mean SD Dermatology Life Quality Index scores from baseline to week 4 was 0.34 (± 0.62, P=0.039).

CONCLUSION:

The results of this preliminary study support the efficacy and safety of sertaconazole nitrate cream, 2%, for the treatment of seborrheic dermatitis