ABSTRACT

Objectives
The objectives of the study were to compare the efficacy and safety of three different concentrations of calcipotriol soft cream (10, 25, and 50 µg/g) and the vehicle of calcipotriol soft cream in the treatment of mild to moderate psoriasis vulgaris of the face.

Methods
The study was a multicentre, randomised, double-blind, parallel group, dose-ranging study. Included were patients of either sex, aged ≥ 18 years, with mild to moderate facial psoriasis who had given their signed informed consent. Excluded were patients whose facial psoriasis was markedly deteriorating or improving spontaneously, patients who currently had facial seborrheic dermatitis, those applying or needing calcipotriol elsewhere on the body apart from the scalp, and those who had been recently using systemic antipsoriatic therapy. Hypercalcaemia, impaired renal and/or hepatic function, intake of calcium tablets or > 400 iu. vitamin D and/or 5,000 iu. vitamin A daily were also exclusion criteria.

Following a 2 week wash-out/qualification phase patients, were randomly assigned treatment with 10 µg/g, 25 µg/g or 50 µg/g or vehicle to treat their facial and scalp psoriasis. Treatment was two times daily for up to 6 weeks.

At baseline and after 1, 2, 4 and 6 weeks, the extent and severity of the facial psoriasis was assessed and an overall efficacy assessment was made. Adverse events observed by either the patient or investigator were recorded. Haematology and biochemical parameters were measured at baseline and at the end-of-treatment visit. Cosmetic acceptability was assessed by the patient at the end-of-treatment visit. The primary efficacy criterion was the change in Total Sign Score (TSS) from baseline (visit 2) to end of treatment.

RESULTS
All treatment groups had a statistically significant effect in terms of reducing the Total Sign Score from baseline to end of treatment. The Intention-To-Treat analysis, showed that the reduction of the Total Sign Score between baseline and the end-of-treatment was significantly higher in the 3 groups receiving calcipotriol (10, 25, 50 µg/g) than in the group receiving...
vehicle only. Further, the 50 µg/g treatment was significantly more effective than the 10 µg/g treatment.

**Primary Efficacy Criterion, Comparison of treatment groups by the Duncan's Multiple Range Test, Intention-to-Treat-Analysis.**

| Treatment               | n  | Mean change (range) | Letters indicate statistically homogeneous treatments
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Vehicle</td>
<td>124</td>
<td>-1.09 (-6 to 5)</td>
<td>A</td>
</tr>
<tr>
<td>Calcipotriol 10 µg/g</td>
<td>124</td>
<td>-2.10 (-8 to 4)</td>
<td>B</td>
</tr>
<tr>
<td>Calcipotriol 25 µg/g</td>
<td>122</td>
<td>-2.33 (-6 to 5)</td>
<td>B</td>
</tr>
<tr>
<td>Calcipotriol 50 µg/g</td>
<td>122</td>
<td>-2.72 (-7 to 4)</td>
<td>C</td>
</tr>
</tbody>
</table>

1) Sum of scores for redness, thickness and scaliness.
2) Treatments with the same letters are not significantly different.

The reduction in extent scores did not differ between treatment groups.

Calcipotriol soft cream 50 µg/g, 25 µg/g and 10 µg/g were also significantly different from vehicle in reducing scores for redness, thickness and scaliness.

Calcipotriol soft cream 50 µg/g was significantly different from calcipotriol soft cream 10 µg/g in reducing scores for thickness.

Calcipotriol soft cream 50 µg/g and 25 µg/g were not significantly different in any respect.

In the investigators' overall assessment, calcipotriol soft cream 50 µg/g, 25 µg/g and 10 µg/g were significantly different from vehicle, and calcipotriol soft cream 50 µg/g was significantly different from calcipotriol soft cream 10 µg/g.

In the patients' overall assessment, calcipotriol soft cream 50 µg/g, 25 µg/g and 10 µg/g were significantly different from vehicle.

**Adverse events** judged possibly or probably related to use of study medication were reported by:

- 37 patients given vehicle (29.8%)
- 56 patients given 10 µg/g (45.2%)
- 60 patients given 25 µg/g (49.6%)
- 65 patients given 50 µg/g (52.8%).
In all treatment groups, lesional/perilesional irritation was the most frequently reported adverse event.

Withdrawals due to adverse events occurred in 9.7% of patients using vehicle, 17.7% of patients using 10 μg/g, 19.7% of patients using 25 μg/g and 15.4% of patients using 50 μg/g. In each group, the majority of these withdrawals occurred in the first 2 weeks of treatment.

Calcipotriol treatment had no effect on s-calcium or any other haematology/biochemical parameters measured.

**Conclusion**

Calcipotriol soft cream, applied twice daily for 6 weeks was efficacious in the treatment of mild/moderate facial psoriasis. The efficacy was dose/concentration related and all creams containing calcipotriol were superior to the vehicle.

Adverse events were more frequent in all active treatment groups containing calcipotriol than in the vehicle group, but no significant differences were found in adverse event frequency among the active treatment groups containing calcipotriol.

No clinically significant changes of any tested laboratory parameters, including mean serum calcium, was observed in any of the treatment groups.