ABSTRACT

Comparison of Calcipotriol Ointment with Betamethasone 17-valerate Ointment and Dithranol and investigation of the Long-term Safety and Efficacy of Calcipotriol

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Calcipotriol ointment (50 μg/g) has been compared with betamethasone valerate (0.1%) and short contact dithranol treatment in large, multicentre, randomized studies on patients with chronic plaque psoriasis.

The first of these was a double-blind, right/left comparison of calcipotriol and betamethasone in 345 subjects. Each treatment was applied twice daily for 6 weeks. Response was assessed by investigators using the PASI, and by subjects on a five-point scale. There was a significant difference in PASI in favour of calcipotriol after 2 weeks, which persisted throughout the study. Subjects' grading of response also significantly favoured calcipotriol.

A second double-blind study, in which 405 subjects participated, compared the same treatments, using the same parameters, but a parallel-group format. Although there was a marked improvement in both groups, there was no significant difference in improvement of the PASI between the two treatments. However, subjects' grading of response again showed calcipotriol to be significantly more effective. Follow-up of subjects in both these studies showed little difference between treatments regarding the frequency, timing and severity of relapse. Further treatment with calcipotriol rapidly brought the disease back under control.

Calcipotriol has been compared with short-contact dithranol therapy in an open, parallel-group study. Two evenly matched groups of 239 subjects were treated for 8 weeks. Calcipotriol was applied twice daily and dithranol cream was applied daily for 30 min at the highest concentration tolerated. The improvement in PASI was significantly better with calcipotriol. Subjects graded both the response to treatment and cosmetic acceptability on five-point scales. The results differed significantly, in favour of calcipotriol, for both parameters.

Long-term use of calcipotriol has also been investigated. Continuing efficacy and safety have been demonstrated in large multi-centre trials performed both by dermatologists, in a study performed on 167 subjects, and by family practitioners, in a study with 211 subjects. Clinical improvement occurred most rapidly during the first 2 months of treatment and this was followed by further, but more gradual, improvement over the rest of the year.

Adverse events were carefully monitored throughout these studies.

Approximately 20% of subjects in the short-term trials experienced some irritation of the skin but this was rarely severe. Over the course of 12 months a larger proportion of subjects reported some degree of irration but very few discontinued treatment as a result. Although the treated areas were most commonly affected, the face was another common site for irritant reactions. There were no increase in the mean serum calcium in any study. Hypercalcaemia did not develop in any subject using the treatment as directed. One subject, who used 400 g of ointment over 10 days, developed asymptomatic hypercalcaemia which resolved promptly after stopping treatment.

These studies have shown calcipotriol to be more effective than betamethasone or short-contact dithranol. It remains effective in long term use as well as being safe and generally well tolerated.

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