

***Aanvraag en verantwoording voor terugbetaling van de farmaceutische specialiteiten  
(klasse 2B):***

***Calcipotriol Sandoz 50 µg/g, 30 g crème – hybrid geneesmiddel***

***Calcipotriol Sandoz 50 µg/g, 120 g crème – hybrid geneesmiddel***

**Betreft: beoordelingsrapport dag 50**

Geachte heer, mevrouw

Wij hebben het beoordelingsrapport dag 60 van de bovenstaande specialiteiten goed ontvangen.

Gelieve in bijlage ons antwoord op dit beoordelingsrapport terug te vinden.

Met de meeste hoogachting

## **Response to question by RIZIV on incidence of itching in trial of Sandoz Calcipotriol Cream**

**Question : 'The commission notices that, concerning the adverse events, itching is reported twice as much in the Calcipotriol Sandoz group than in the Daivonex group. How can this difference be explained? Do excipients play a role in this? '**

### **Response :**

The actual reported incidence of itching in the group of patients treated with Sandoz Calcipotriol Cream was 12% (13/108) and for Daivonex was 7% (8/108). The incidences of other dermatological adverse effects were as follows (Calcipotriol versus Daivonex, respectively) : erythema 6% vs 8%, skin irritation 7% vs 5%, burning skin 3% vs 5%. In other words, some symptoms are apparently slightly commoner with Calcipotriol Cream, and others slightly commoner with Daivonex Cream. All these symptoms are part of the spectrum of those associated with the disease itself (psoriasis) and it is therefore difficult to separate these from true adverse effects as a result of the trial medication. The intensity of the symptoms were classified as mild or moderate in the majority of patients. The apparent differences in incidence of skin symptoms (in particular itching) are not statistically significantly different between the groups and the findings are almost certainly chance findings. The incidences are also in keeping with those reported in the published literature on calcipotriol.

It is also unlikely that any differences in excipients of the two calcipotriol cream formulations are responsible for any of the apparent differences in itching either, since the only difference in excipients between Sandoz Calcipotriol Cream and Daivonex Cream is the addition of a minute quantity (0.1 mg/g) of sodium dihydrogen phosphate dihydrate to the Sandoz formulation as buffering agent (see table below) and it is clinically highly unlikely that this would be responsible for any aggravation of skin symptoms.

### **Comparison of qualitative and quantitative composition specified per 1.00g of cream**