# Long-term treatment of plaque psoriasis with calcipotriene/betamethasone dipropionate foam was locally well tolerated and not associated with skin atrophy

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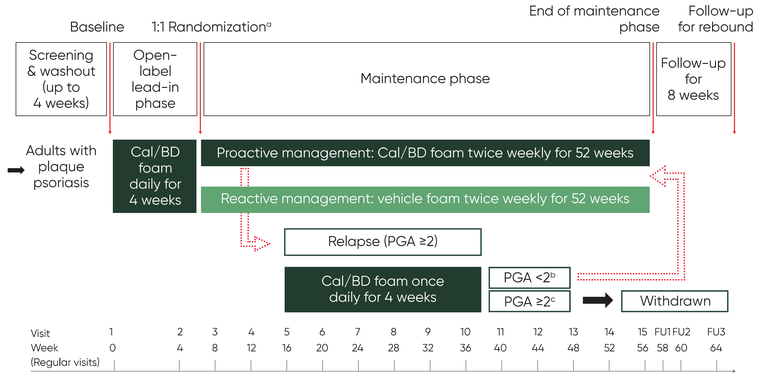
## Introduction

- An unmet need exists for the long-term treatment of plaque psoriasis with topical therapies[1]
  - Conventional long-term treatment of plaque psoriasis with topical therapies uses a reactive approach where the treatment is used after relapse has occurred versus a proactive approach to maintain remission[2,3]
  - Proactive treatment is a well-established treatment concept for moderate-to-severe atopic dermatitis[4]
- The phase 3 PSO-LONG study showed that proactive management versus reactive management using calcipotriene 0.005%/betamethasone dipropionate 0.064% (Cal/BD) foam for up to 52 weeks in adults with psoriasis delayed time to first relapse, significantly extended time in remission, and reduced the number of relapses per year[5]
- Skin atrophy is a concern with long-term use of topical steroids[6]
- In this analysis of data from the PSO-LONG study, we evaluated skin atrophy and local tolerability

## Methods

- PSO-LONG (NCT02899962) included an initial 4-week open-label phase (once-daily Cal/BD foam) and a 52-week, double-blind, maintenance phase where patients were randomized to twice-weekly Cal/BD foam or vehicle foam, with a 4-week once-daily Cal/BD foam rescue treatment for relapse (Physician Global Assessment [PGA] ≥2) (proactive management or reactive management, respectively) (**Figure 1**)
- Physician assessments of local skin reactions (dryness, erosion, erythema, edema, and burning/pain) were conducted at unscheduled visits or at regular visits (every 4 weeks). Other local skin reactions (ie, skin atrophy) were reported if observed during the visits

**Figure 1.** Trial design




[a]Patients with treatment success at end of open-label lead-in phase (PGA score 'clear'/'almost clear' [PGA <2] with ≥2-grade improvement from baseline) were randomized 1:1 in the maintenance phase

[b]Following 4 weeks of once-daily rescue treatment, patients who regained PGA<2 ('clear'/'almost clear') re-started the twice-weekly maintenance treatment according to the original randomization scheme

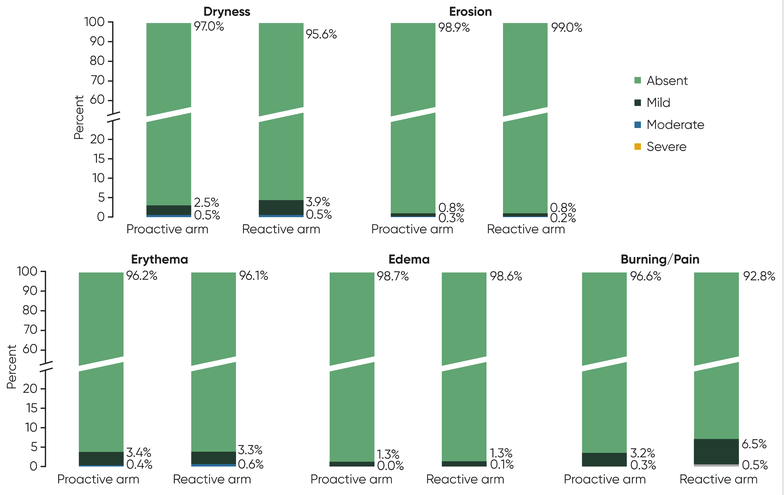
[c]Patients who did not regain a PGA score <2 ('clear'/'almost clear') following 4 weeks of once-daily rescue treatment were withdrawn from the trial

Cal/BD, calcipotriene 0.005%/betamethasone dipropionate 0.064%; FU, follow-up; PGA, Physician Global Assessment

## Results

- The analysis included 545 patients (proactive arm, n=272; reactive arm, n=273)
  - Most of the patients in the study were men (68%), white (91%), with an average age of 52 (±14 standard deviation) years and had PGA-moderate psoriasis (82%)
- When evaluating regular visits (non-relapse-related, ie, assessments done at visits where the patient is not starting or ending relapse, or in a relapse) (**Figure 2**), physicians reported:
  - No dryness (97.0% proactive arm vs. 95.6% reactive arm)
  - No erosion (98.9% proactive arm vs. 99.0% reactive arm)
  - No erythema (96.2% proactive arm vs. 96.1% reactive arm)
  - No edema (98.7% proactive arm vs. 98.6% reactive arm)
- Patients reported no burning/pain (96.6% proactive arm vs 92.8% reactive arm)

**Figure 2.** Assessments of local skin reactions not related to relapse




Patients in the proactive arm (n=272) versus the reactive arm (n=273)

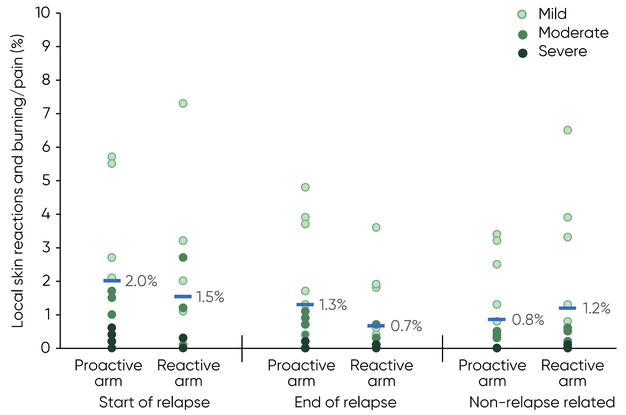
Percentages are taken out of the total number of assessments done at visits (proactive arm 1517 visits; reactive arm 953 visits) where a relapse is not starting, ending, or ongoing (not related to relapse)

Only Burning/Pain had a severe assessment (0.1%)

Cal/BD, calcipotriene 0.005%/betamethasone dipropionate 0.064%

- At the start and end of relapses, local skin reactions and burning/pain were present at slightly higher levels than non-relapse-related visits (**Figure 3**) but were still absent for the majority (≥89.8%) of patients in both treatment groups, with cases that were usually mild
- Skin atrophy was not reported by investigators at any point, in either treatment group

**Figure 3.** Assessments of local skin reactions and burning/pain[a]




[a]All assessments of skin reactions and burning/pain are combined in this plot

Patients in the proactive arm (n=272) versus the reactive arm (n=273)

Each circle represents the percentages of patients reporting either "Mild", "Moderate", or "Severe" assessment at the start or end of a relapse, or non-relapse related to dryness, erosion, erythema, edema, and burning/pain

Percentages are taken out of the total number of assessments done at visits where a relapse is started, a relapse is ended, or where a relapse is not starting, ending, or ongoing (non-relapse related), respectively

The mean percentage of patients reporting a skin reaction/burning/pain across skin types is shown by the blue bars

Cal/BD, calcipotriene 0.005%/betamethasone dipropionate 0.064%

## Conclusions

- Cal/BD foam was well tolerated in patients with psoriasis when used as either reactive or proactive management for up to 52 weeks, with low reports of local skin reactions and burning/pain, and no safety reporting of skin atrophy.

### References

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