

# Patient Preference for Calcipotriene 0.005%/Betamethasone Dipropionate 0.064% Foam or Topical Suspension vs. Latest Topical Treatment in the PSO-INSIGHTFUL Study

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## Introduction

- Topical therapies are a mainstay in psoriasis vulgaris treatment and are used in combination therapy even in patients receiving systemic or biologic therapy
- Patient preference for vehicle formulation can impact adherence and, consequently, real-life effectiveness
- The PSO-INSIGHTFUL study was designed to assess patient-reported factors that influence preference following once-daily topical treatment with calcipotriene 0.005%/betamethasone dipropionate 0.064% (Cal/BD) foam and gel<sup>1</sup>
- Questionnaires (including Topical Product Usability Questionnaire, TPUQ; Comparison to Latest Topical Treatment, CLTT) were completed by patients at baseline and timepoints during the study to assess usability and preference differences

## Materials & Methods

### PSO-INSIGHTFUL Study Design

- PSO-INSIGHTFUL was a prospective, multicenter, Phase IIIb, open-label, randomized, two-arm crossover study including patients  $\geq 18$  years with mild-to-severe psoriasis of  $\geq 6$  months' duration involving 2-30% BSA and mPASI of  $\geq 2$  (Table 1)
- After 4-week washout, 213 patients were randomized 1:1 to once-daily Cal/BD foam for 1 week, followed by Cal/BD gel for 1 week, or vice-versa (Figure 1)

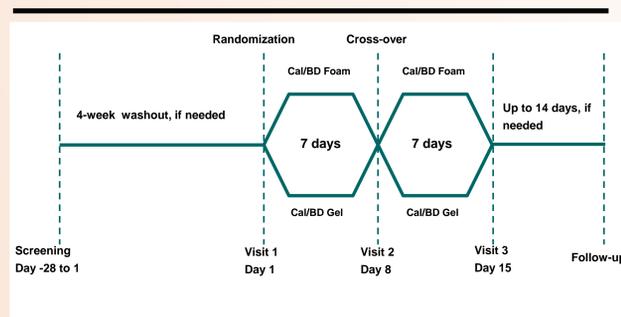


Figure 1: Schematic of study design of PSO-INSIGHTFUL, [NCT02310646]<sup>2</sup>

### Study Assessments

- Patients completed questionnaires to assess therapy usability and preference differences
  - Topical Product Usability Questionnaire (TPUQ)
  - Comparison to Latest Topical Treatment (CLTT)

### Statistical Analysis

- Full analysis set comprised all randomized patients who completed an on-study questionnaire
- LTT analysis set comprised all randomized patients who had used topical treatment within 3 months before baseline

Table 1. Patient Demographics and baseline characteristics (adapted from PSO-INSIGHTFUL)

	All patients n = 212 (%)
<b>Age category, n (%)</b>	
18 – 39 years	48 (22.6)
40 – 59 years	92 (43.4)
$\geq 60$ years	72 (34.0)
<b>Male : Female, n (%)</b>	133:79 (63:37)
<b>BMI, n (%)</b>	
< 25 kg/m <sup>2</sup>	37 (17.5)
25 – 30 kg/m <sup>2</sup>	73 (34.4)
> 30 kg/m <sup>2</sup>	102 (48.1)
<b>PGA, n (%)</b>	
Mild	61 (28.8)
Moderate	122 (57.5)
Severe	29 (13.7)
<b>Duration of psoriasis, n (%)</b>	
< 2 years	4 (1.9)
2 – 5 years	30 (14.2)
> 5 years	178 (84.0)
<b>BSA, n (%)</b>	
< 4%	93 (43.9)
4 – 6%	56 (26.4)
6 – 11%	38 (17.9)
11 – 15%	11 (5.2)
$\geq 15\%$	14 (6.6)
<b>mPASI, n (%)</b>	
2 – 5	86 (40.6)
5.1 – 10	91 (42.9)
> 10	35 (16.5)
<b>Mean DLQI</b>	7.8
<b>Localized:widespread distribution of psoriasis, %</b>	62:38

BMI, body mass index; BSA, body surface area; mPASI, modified psoriasis and severity index; PGA, Physician's Global Assessment of disease severity

## Results

Table 2. Mean TPUQ scores compared with LTT, by domain, for Cal/BD foam and topical suspension

	LTT (n=118)	Cal/BD foam (n=116)	Cal/BD topical suspension (n=115)
<b>Application domain scores</b>			
Ease of application	1.4	1.2	1.5
Ease of application on lesion only	1.3	0.9*	1.4
Ease of spreading	1.5	1.5	1.7*
Lack of mess	0.6	0.9	1.0**
Good for use on small areas	1.1	1.0	1.4*
Good for use on large areas	0.9	1.4***	1.5***
Quick to apply	1.2	1.5**	1.3
Total time spent acceptable	1.1	1.6***	1.4**
Easily incorporated into daily routine	1.0	1.5***	1.4***
<b>Formulation domain scores</b>			
Quickly absorbed	0.2	0.7**	0.6**
Dried quickly	0	0.5**	0.4**
Immediate feeling of relief	0.1	1.1***	0.7***
Felt soothing	0.6	1.3***	1.0**
Appealing to touch	0.2	1.0***	0.9**
Felt moisturizing	0.6	1.3***	1.2**
Not greasy	-0.5	0.2**	0.2**
Odourless	1.2	1.3	1.5**
No staining	0.4	0.9*	0.9**
<b>Container domain scores</b>			
Easy to get medication out of container	1.3	1.2	1.3
Easy to use	1.3	1.2	1.4
Easy to keep clean	1.1	1.3	1.3
Accurately dispense wanted amount	1.0	0.9	1.5**
<b>Satisfaction domain scores</b>			
Confidence in using	0.6	1.3***	1.2***
Would use regularly	0.9	1.4**	1.3*
Would recommend	0.4	1.3***	1.0**
<b>Overall satisfaction</b>	0.3	1.2***	1.1**

Range: -2, strongly disagree to +2, strongly agree  
\*P<0.05; \*\*P<0.01; \*\*\*P<0.001 vs LTT. LTT included various corticosteroids (of different potencies) and combination products, with similar types of products in all categories (ointment, cream, 'other')

### Cal/BD foam or Cal/BD topical suspension vs. LTT:

- Mean TPUQ domain scores were often significantly in favor of both Cal/BD foam and topical suspension compared with LTT
- Scores for Cal/BD topical suspension were generally higher than for LTT
- Most scores for Cal/BD foam were higher, although some related to ease of application and container items were comparable to LTT

### Topical Product Usability Questionnaire (TPUQ)

- Each patient assessed the extent to which they agreed with each of the 26 items using 5-point scale (-2 to 2), organized into four domains: "application", "formulation", "container", "satisfaction," regarding product usability.
- Frequency:
  - Following randomization, the TPUQ was used to assess the LTT at baseline
  - During visits to the clinic at the end of weeks 1 and 2, patients completed TPUQ based on their treatment experience during the previous 7 days

### Comparison to Latest Topical Treatment (CLTT)

- Patients stated whether they preferred their LTT or Cal/BD foam/gel, or had no preference
- Frequency:
  - During visits to the clinic at the end of weeks 1 and 2, patients completed CLTT based on their treatment experience during the previous 7 days

Table 4. Difference in total formulation score (TPUQ) between study treatments by psoriasis distribution phenotype (FAS)

	All patients; foam-gel*
<b>Localized (n = 128)</b>	0.5 $\pm$ 8.8
<b>Widespread (n = 78)</b>	-2.1 $\pm$ 8.2
<b>All patients (n = 204)</b>	-0.5 $\pm$ 8.2

\*Negative difference indicates preference for gel

### Differences in TPUQ scores between study treatments by psoriasis distribution

- The forward selection procedure identified psoriasis distribution as a significant factor
- Trend towards more favorable scores for Cal/BD foam in patients with localized distribution and in favor of gel for patients with widespread distribution

## Conclusions

- Overall, patients from the PSO-INSIGHTFUL study had stronger preferences for either Cal/BD foam or gel as compared to their last topical treatment
- These results from the Topical Product Usability Questionnaire are further corroborated with the similar results in the Comparison to Latest Topical Treatment survey
- The significant differences observed in favor of Cal/BD foam as compared to the topical suspension formulation are related mainly to application and a "feeling of relief" which may be attributable to the vehicle
- These data provide insight into aspects of topical product usability, but more robust research is necessary to obtain a complete understanding

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## References

<sup>1</sup> Hong C-H, Papp KA, Lophaven KW, et al. Patients with psoriasis have different preferences for topical therapy, highlighting the importance of individualized treatment approaches: Randomized Phase IIIb PSO-INSIGHTFUL study [submitted].

<sup>2</sup> ClinicalTrials.gov. Bethesda (MD): National Library of Medicine (US). 2017 Jun 1. Identifier: NCT02310646. Patient Insights Following Use of LEO 90100 Aerosol Foam and Daivobet® Gel in Subjects With Psoriasis Vulgaris. <https://clinicaltrials.gov/ct2/show/NCT02310646?term=NCT02310646&rank=1>