

# Patient Preferences for Vehicle and Overall Preference of Calcipotriene 0.005%/Betamethasone Dipropionate 0.064% Foam and Gel in the PSO-INSIGHTFUL Study

Chih-Ho Hong, MD<sup>1</sup>, Dharm S. Patel, PhD<sup>2</sup>, Katja Wendicke Lophaven, MSc<sup>2</sup>

<sup>1</sup>University of British Columbia, Department of Dermatology and Skin Science and Probitry Medical Research, <sup>2</sup>LEO Pharma

## Introduction

- Topical therapies are the first-line treatment for mild-to-moderate plaque psoriasis or are used in combination with other therapies for severe disease.<sup>1</sup>
- Patient compliance to topical therapy is a significant issue, with adherence rates estimated at 40-70%.<sup>2</sup> Patient preference for vehicle formulation can impact adherence, and thus, real-life effectiveness.<sup>3</sup>
- The PSO-INSIGHTFUL study was designed to gain insight on patient reported factors that influence preference following once-daily topical treatment with calcipotriene 0.005%/betamethasone dipropionate 0.064% foam and gel.
- Subjects' Preference Assessment (SPA) and Vehicle Preference Measure (VPM) were completed by patients to assess preference differences based on vehicle and overall preference of Cal/BD foam and gel.

## Materials & Methods

### PSO-INSIGHTFUL Study Design

- PSO-INSIGHTFUL was a prospective, multicenter, Phase IIIb, open-label, randomized, two-arm crossover study held in Germany and Canada (NCT02310646)<sup>4</sup>
- Adult patients ≥ 18 years with mild-to-severe psoriasis of ≥ 6 months' involving 2-30% body surface area (BSA) and mPASI ≥ 2 were included in study (Table 1)
- After a 4-week washout period, 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 (Fig 1)

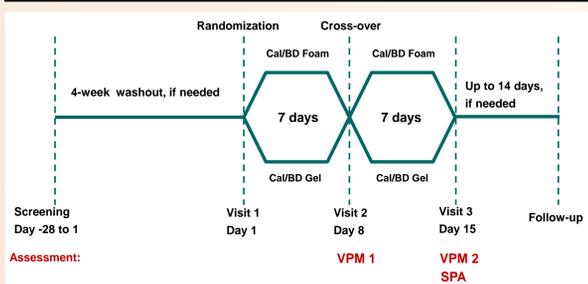


Figure 1: Schematic of study design of PSO-INSIGHTFUL, [NCT02310646]<sup>4</sup>

### Study Assessments

- Patients completed questionnaires to assess therapy usability and preference differences:
  - Subjects' Preference Assessment (SPA) – developed by LEO Pharma
  - Vehicle Preference Measure (VPM) – Wake Forest Health Sciences<sup>5</sup>

### Statistical Analysis

- SPA: individual baseline characteristics were examined in a two-factor logistic regression model including treatment sequence and various baseline characteristics as factors.
- The full analysis set (FAS) comprised all randomized patients who completed an on-study questionnaire.

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)
≥ 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)
≥ 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

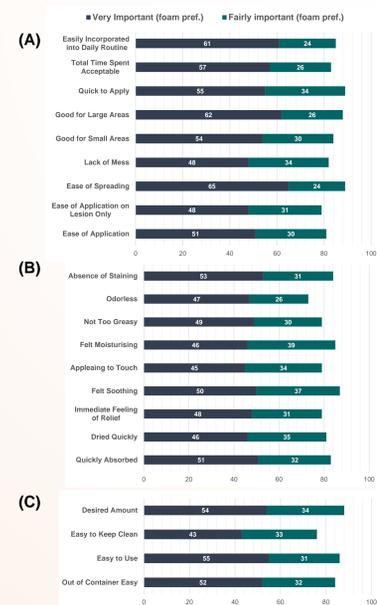


Figure 2: Reasons for preference of Cal/BD foam (SPA): (a) Application; (b) Formulation; and (c) Container items (FAS).

### Subjects' Preference Assessment (SPA)

- Equal preference of subjects preferring foam and the other half gel (Table 2)
- Logistic regression analysis performed to identify baseline characteristics driving preference choices:
  - A difference in preference between *age category* was observed (Table 2)
  - No robust findings on other baseline characteristics (e.g. gender, disease severity, phenotype)
- Reason for preference not very discriminant, however:
  - For **foam**, size of application area and items related to feeling of relief/soothing seems to be a preference factor (Fig 2)
  - For **gel**, precision of application seems to be preference factor (Fig 3)

### Subjects' Preference Assessment (SPA)

- At the end of week 2 visit, patients completed:
  - SPA: Comprised of two domains, the patient indicated:
    - (a) if they preferred Cal/BD foam or gel based on the previous 14 days; and
    - (b) how much each of the 22 application-, formulation and container-related items contributed to their overall preference using a four-point scale ranging from 'very important' to 'not at all important'

### Vehicle Preference Measure (VPM)

- At the end of weeks 1 and 2, patients completed questionnaire based on their treatment experience during the previous 7 days:
  - VPM: Comprised seven items that were assessed on a seven-point scale ranging from -3, 'extremely unappealing', to +3, 'extremely appealing'

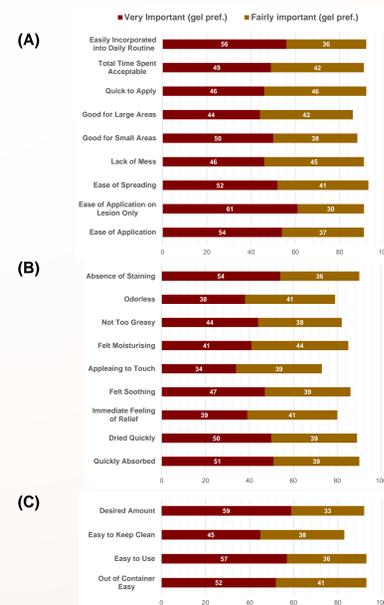


Figure 3: Reasons for preference of Cal/BD gel (SPA): (a) Application; (b) Formulation; (c) Container items (FAS).

Table 2. Overall patient preferences, by age, for Cal/BD foam or gel.

Age Class	Prefer Foam	Prefer Gel
<b>All (n=208)</b>	49.5%	50.5%
<b>- 18-39 years (n=48)</b>	72.9%	27.1%
<b>- 40-59 years (n=90)</b>	44.4%	55.6%
<b>- &gt;=60 years (n=70)</b>	40.0%	60.0%

Table 3. Vehicle Preference Measure (VPM) for Cal/BD foam and gel.

	Foam Mean (n=211)	Gel Mean (n=210)
Ease of application	1.5	1.9
Time it takes to apply	1.9	2.0
How well it is absorbed	1.4	1.4
How it feels to touch	1.4	1.6
How it smells	1.6	1.9
How it feels on the skin	1.8	1.8
How much it stains	1.4	1.3

### Generally high scores for both Cal/BD foam and gel (Table 3):

- The highest mean scores for **foam** for:
  - 'time it takes to apply'
  - 'how it feels on the skin'
- The highest mean scores for **gel** for:
  - 'time it takes to apply'
  - 'ease of application'
  - 'how it smells'
- No major difference between treatments (significant for odor)

## Conclusions

- The PSO-INSIGHTFUL study demonstrated that overall patient preference was similar between Cal/BD foam and gel.
- Main drivers for patients preferring Cal/BD foam over gel were items related to sensation (i.e. 'immediate feeling of relief' and 'felt soothing to skin')
- Cal/BD gel scored higher vs foam for items related to ease of application, time it takes to apply, and odor.
- Cal/BD foam was generally preferred by younger patients (aged 18-39 years), whereas Cal/BD gel tended to be preferred by older patients (aged ≥40 years).
- PSO-INSIGHTFUL study demonstrates that psoriasis patients have diverse needs and different preferences for topical treatment, which can influence adherence and outcomes.

## Acknowledgements

This study was sponsored by LEO Pharma.

## References

- Nast, A. et al. European S3-Guidelines on the systemic treatment of psoriasis vulgaris-Update 2015--Short version--EDF in cooperation with EADV and IPC. J. Eur. Acad. Dermatol. Venereol. J. EADV 29, 2277-2294 (2015).
- Devaux, S. et al. Adherence to topical treatment in psoriasis: a systematic literature review. J. Eur. Acad. Dermatol. Venereol. 26, 61-67 (2012).
- Feldman, S. R. et al. Psoriasis: improving adherence to topical therapy. J. Am. Acad. Dermatol. 59, 1009-1016 (2008).
- NCT02310646 - Patient Insights Following Use of LEO 90100 Aerosol Foam and Daivobet® Gel in Subjects With Psoriasis Vulgaris. Available at: <http://www.clinicaltrials.gov/ShowTrial/NCT02310646>. (Accessed: 3rd November 2017)
- Housman, T. S., Mellen, B. G., Rapp, S. R., Fleischer, A. B. & Feldman, S. R. Patients with psoriasis prefer solution and foam vehicles: a quantitative assessment of vehicle preference. Cutis 70, 327-332 (2002).