Patient Insights in Topical Therapy in Psoriasis

Dr. Kim Papp
Speaker Disclosures

Speaker, Consultant, Investigator

- Amgen ***
- Anacor ***
- AbbVie ***
- Active Biotech *
- Akesis *
- Allergan **
- Astellas ***
- AstraZeneca **
- Basilea **
- Bayer **
- Biogen-Idec *
- Boehringer-Ingelheim ***
- Bristol Myers Squibb **
- Celgene ***
- Cato *
- CellScale Biomaterials *
- Cepheid *
- Centocor ***
- Cipher *
- Coherus **
- Dow Pharma *
- Eli Lilly ***
- Endocyte *
- Ferring Pharma *
- Forward Pharma **
- Galderma ***
- Genentech **
- Gilead **
- GSK **
- Janssen ***
- Kyowa Hakko Kirin **
- Kythera **
- LEO Pharma ***
- Medimmune **
- Meiji Seika Pharma *
- Merck (MSD) ***
- Mylan ***
- Merck-Serono ***
- Novartis ***
- Pfizer ***
- Regeneron ***
- Rigel *
- Roche **
- Sosei *
- Takeda **
- Takeda **
- Sanofi-Aventis *
- UCB ***
- Vertex *
- Xoma **
Barriers

- Medication efficacy
- Messiness
- Time-consuming/complex regimens
- Inconvenient
- Side effects

What do our patients think?

What is adherence?

What are the long-term effects?

What if I miss a dose?

Do I take with food?

How do I take the medication?
Breaking Barriers

- Effective
- Cosmesis
- Convenient
- Simple
- Safe
The Patient Gap

Using patient insight to get better patient outcomes

- Involvement of patients in product development
  - Ex: Dovobet® Gel Applicator
- Patient Advocacy Groups
Calcipotriol & Betamethasone Dipropionate Evolution

Dovobet® Ointment (Calcipotriol/betamethasone dipropionate) 2001

1995
Dovonex® (Calcipotriol)
Cream, Ointment, Scalp Solution

Calcipotriol/Betamethasone Dipropionate Formulation

- Unique anhydrous formulation allows disparate substances to co-exist
- Maintains bioavailability

Stability

BDP Calcipotriol
0 7 14 pH
Enstilar® - Ingredients and Properties

Enstilar® - Ingredients and Properties

- **Vehicle base** (paraffin + additives)
- **50 µg/g calcipotriol (Cal) (as monohydrate)**
- **0.5 mg/g betamethasone dipropionate (BD)**
- **Propellants (butane & dimethyl ether)**

Highlights from the PSO INSIGHTFUL STUDY
Study Objective
Attributes effecting usability
Factors influencing patient preference
PSO-Insightful Study Design

International, multi-centre, prospective, open-label, randomised, 2-arm, 2-week cross-over trial, N=200

- Screening: Day -28 to 1
- Randomisation: Visit 1 (Day 1) - Enstilar® Aerosol Foam
- Cross-over: Visit 2 (Day 8) - Dovobet® Gel
- Visit 3 (Day 15) - Follow-up

4-week washout, if needed

Up to 14 days, if needed
Main Assessments

- Disease severity via PGA, BSA, mPASI, SGA (baseline measures)
- Dermatology Life Quality Index (DLQI) (validated)
- Subject’s Assessment of Behaviour and Attitudes (SABA)
- Vehicle Preference Measure (VPM) *(Licensed from Wake Forest Health Sciences) (validated)*
- Comparison to Latest Topical Treatment (CLTT)*
- Product Usability Questionnaire (TPUQ)
- Subject’s Preference Assessment (SPA)

*Only relevant for subjects that have used a topical anti-psoriatic treatment on treatment areas within last 3 months*
<table>
<thead>
<tr>
<th><strong>PSO-Insightful: Patient Demographics</strong></th>
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<table>
<thead>
<tr>
<th><strong>Age</strong></th>
<th>52 years; 37% female (mean)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Duration of psoriasis</strong></td>
<td>20 years (mean)</td>
</tr>
</tbody>
</table>
| **Disease severity**       | • BSA (trunk/limbs): 5.7% (mean)  
  • Baseline PASI: 6.8 (mean)  
  • PGA: mild 29%, moderate 57%, severe 14% |
| **DLQI score**      | 7.8 (mean)                   |
| **N**               | • 212 subjects - Full analysis set  
  • 118 subject - CLTT analysis set |
Assessment of Psoriasis
Subject’s Assessment of Behaviour and Attitudes (SABA)

**Impact of Psoriasis (yes/no)**

- Impacts my work
- Impacts my social life
- Impacts my relationship/sex life
- Physical impact
- Impacts my self-confidence
- Impacts my well-being

**Attitude to Psoriasis (5 pt scale)**

- I prefer my doctor to recommend
- I regularly seek out information on psoriasis
- Keen to try the newest treatment
- Apply treatment quickly very important
- Busy lifestyle Limits Time for Treatment
- Worry about side effects
- Feels very self-conscious about psoriasis

Slightly agree

Strongly agree
On each table you will find:

- Enstilar® Aerosol Foam Vehicle (Placebo)
- Dovobet® Gel Vehicle (Placebo)

Sample each vehicle on your skin:

- **Foam**: Shake well - spray 3 cm from your skin
- **Gel**: Shake well - apply to your skin
  - Rub each formulation into your skin

Consider the following characteristics for each product:

- Application: ease and spreadability
- Formulation: sensation and cosmetic properties
Question

In your opinion, which of the following differentiates Enstilar® from Dovobet® Gel?

i. Quickly absorbed
ii. Soothing feeling on skin
iii. Ease of application
iv. Lack of mess when applying
v. Not greasy
What do you think patients will feel differentiates Enstilar® from Dovobet® gel?

i. Quickly absorbed
ii. Soothing feeling on skin
iii. Ease of application
iv. Lack of mess when applying
v. Not greasy
What other characteristics would you use to describe Enstilar®?

i. Not greasy

ii. Cool feeling on application

iii. Quick to apply

iv. Good for use on large areas
Product Assessments:

Enstilar® Aerosol Foam - Dovobet® Gel

- Topical Product Usability Questionnaire (TPUQ)
- Comparison to Last Topical Treatment (CLTT)
- Vehicle Preference Measure (VPM)
Topical Product Usability Questionnaire
Enstilar® Aerosol Foam – Top Scores

Application – Highest scores

- ‘ease of spreading’
- ‘quick to apply’
- ‘total time spent acceptable’
- ‘easily incorporated into daily routine’
- ‘good for large areas’
Topical Product Usability Questionnaire
Enstilar® Aerosol Foam – Top Scores

**Formulation**
- ‘felt soothing’
- ‘odourless’
- ‘felt moisturising to my skin’

**Satisfaction** - Generally high scores
- ‘would use product regularly’
Topical Product Usability Questionnaire
Dovobet® Gel – Top Scores

Application – Highest scores
• ‘ease of spreading’
• ‘ease of application’
• ‘good for use on larger areas’
• ‘total time spent acceptable’
• ‘easily incorporated into daily routine’
**Topical Product Usability Questionnaire**
**Dovobet® Gel – Top Scores**

**Formulation**
- ‘felt soothing’
- ‘odourless’
- ‘felt moisturising to my skin’

**Satisfaction** - Generally high scores
- ‘would use product regularly’
### Topical Product Usability Questionnaire (TPUQ)

**Formulation - What do patients like most about the Foam & Gel**

<table>
<thead>
<tr>
<th>Aerosol Foam</th>
<th>Gel</th>
</tr>
</thead>
<tbody>
<tr>
<td>N=(209)</td>
<td>N=(198)</td>
</tr>
</tbody>
</table>

Rating scale: -2 to +2.
### Topical Product Usability Questionnaire (TPUQ)

#### Difference in Scores Between Treatments

<table>
<thead>
<tr>
<th>Age Groups</th>
<th>Enstilar Aerosol® Foam N=(209)</th>
<th>Dovobet® Gel N=(198)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients 18 to 39 yrs</td>
<td>preferred foam</td>
<td>Patients 40 to 59 yrs and ≥60 yrs preferred gel</td>
</tr>
</tbody>
</table>
**Vehicle Preference Measure (VPM) Questionnaire (7 questions, 7 point scale)**

**What do patients like most about the vehicles?**

<table>
<thead>
<tr>
<th>Foam</th>
<th>Gel</th>
</tr>
</thead>
<tbody>
<tr>
<td>• ‘time it takes to apply’</td>
<td>• ‘time it takes to apply’</td>
</tr>
<tr>
<td>• ‘how it feels on the skin’</td>
<td>• ‘ease of application’</td>
</tr>
<tr>
<td></td>
<td>• ‘how it smells’</td>
</tr>
</tbody>
</table>
Overall Summary

Both treatments showed high scores for usability and satisfaction

**Aerosol Foam** and **gel** are generally preferred over previous topical treatments:
- 72% would recommend **Foam** to other patients
- 66% would recommend **Gel** to other patients
Overall Summary

**Preference** between gel and foam is shared between subjects

- younger patients favoured foam
- older patients favoured gel

**Foam** highlights: ‘immediate feeling of relief’ & ‘felt soothing to my skin’

**Gel** Highlights: ease and precision of application