Clinical Comparison of OTC Products Labeled “Prescription Strength Wetness Protection” to Prescription Antiperspirants

Lola Kelly Smalls, PhD, MBA, Laurie Elstun, MS, Amy Capretta, BS, Laura Lebda, MA, Michael Thomas, MBA, Andrew Setser, BS, Anne Westbrook, BS, Jenny Lam, BS, John Jolicour, BS, David Swaile, PhD, P&G Beauty, Cincinnati, OH

INTRODUCTION

Recently, OTC antiperspirant products with statistically similar efficacy to a prescription antiperspirant product have been introduced to the general market. These antiperspirants “soft solid” products remove barriers to treatment compliance by reducing skin irritation and by optimizing product aesthetics for nighttime treatment. As we have previously presented, nighttime application is capable of significantly improving the efficacy of OTC antiperspirants. This presentation provides additional clinical comparisons of an OTC antiperspirant product to a prescription product in males. Additionally, product performance over a 21-day period in females is shown.

OBJECTIVE

• Compare the antiperspirant efficacy of a prescription strength product vs. a prescription product in males.

• Show the treatment effect of the prescription strength product over a 24-day period in females.

METHODS

A series of three clinical studies were conducted among different populations (n=100 subjects) to further quantify the underarm efficacy performance of an OTC anhydrous, aluminum zirconium trichlorohydrex gly AP relative to a prescription AP containing aluminum chloride (62.5% active). In two clinical studies, male panelists had product applied every evening for up to 9 days following the protocol in Figure 1. In the third clinical study, female panelists had product applied for up to 21 days, with sweat collections on days 7, 10, and 21. The panelists were evaluated for irritation by an expert at each visit. If a panelist had an irritation score of 2 or above, product application was discontinued.

All products were applied following usage instructions. The soft solids were applied at 0.4 g (two clicks) for females and 0.6 g (three clicks) for males. This dose difference accounts for the smaller axilla size (roughly 64 cm²) in females than males (roughly 135 cm²).

RESULTS

Male Testing: In two independent clinical trials (Cincinnati, OH and Phoenix, AZ), the OTC anhydrous “soft solid” AP (Treatment A) provided statistically superior efficacy to the Rx Aluminum Chloride AP (Treatment C) in males at both 6 and 9 days. The subject data from the 24 Hour post-treatment 9 evaluation are presented from both clinicals in Figures 2 & 3. The lower regression line in both figures indicate better sweat reduction.

Figure 2. Clinical Study #1, n=35

Figure 3. Clinical Study #2, n=35

Table 1. Male Clinical Results Summary

<table>
<thead>
<tr>
<th>Treatment</th>
<th>mg sweat Remaining</th>
<th>Difference</th>
<th>Percent Difference</th>
<th>One-sided P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>A (SS) Overall</td>
<td>148 mg</td>
<td>50 mg</td>
<td>-34.0%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>C (Rx) Overall</td>
<td>198 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A (SS) Post 6</td>
<td>155 mg</td>
<td>34 mg</td>
<td>-35.5%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>C (Rx) Post 6</td>
<td>209 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A (SS) Post 9</td>
<td>199 mg</td>
<td>74 mg</td>
<td>-47%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>C (Rx) Post 9</td>
<td>273 mg</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Female Testing: To understand the treatment performance over time, and expected level of benefit a 21-day treatment clinical was placed with 30 female panelists in St. Petersburg, FL. In this test an OTC soft solid was compared to no treatment and sweat collections were performed after 7, 10 and 21 days of product application. The treatment estimates ranged from 59-69% reduction (Figure 4). Moreover, a majority of panelists showed more than 60% sweat reduction over no treatment at each time point (Figure 5). 60% sweat reduction is twice the FDA monograph requirement for an extra effective antiperspirant.

CONCLUSIONS

Overall, nighttime application of an OTC anhydrous AP containing an Aluminum Zirconium Trichlorohydrex Gly active provides an effective alternative to Prescription Aluminum Chloride antiperspirant.

• A soft solid product can provide statistically superior sweat reduction as compared to a Prescription Aluminum Chloride AP in male panelists.

• Nighttime application of a soft solid OTC antiperspirant consistently provides a majority of female users with more than 60% sweat reduction.

References


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