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

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INTRODUCTION

Recently, OTC antiperspirant products with statistically similar efficacy to a prescription antiperspirant product have been introduced to the general market. These anhydrous "soft solid" products remove barriers to treatment compliance by reducing skin irritation and by optimizing product aesthetics for nighttime treatments. As we have previously presented, nighttime application is capable of significantly improving the efficacy of OTC antiperspirant actives. [1,2] 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 female is shown.

OBJECTIVE

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

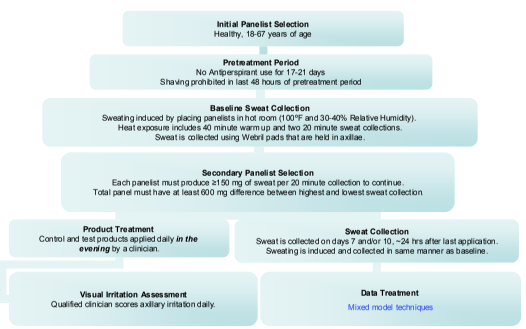
•Show the treatment effect of the prescription strength product over a 21-day period in females.

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 (6.25% 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 during 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 cm^2) in females than males (roughly 135 cm^2). [3]

Figure 1. Clinical Protocol



Data Analysis

Mixed model techniques were used to analyze the gravimetric sweat data. Even if application was discontinued, all subjects were eligible to participate in sweat collection regardless of treatment compliance and were considered in the analyses to provide an estimate representative of actual practice (intent to treat analysis).

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**

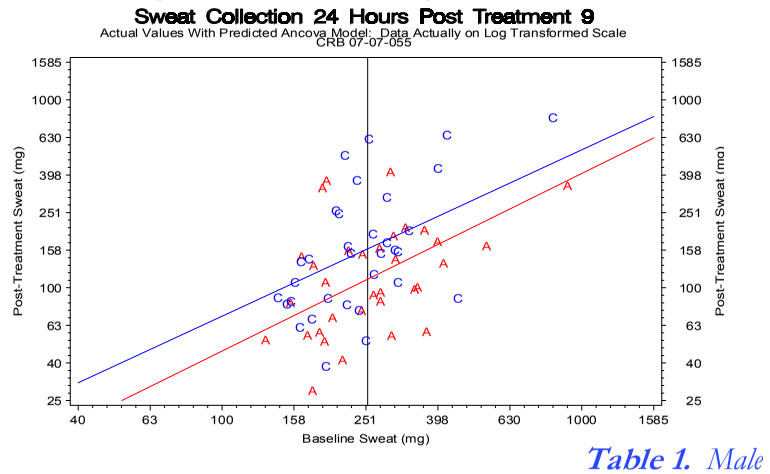


***Figure 3.* Clinical Study #2, n=35**

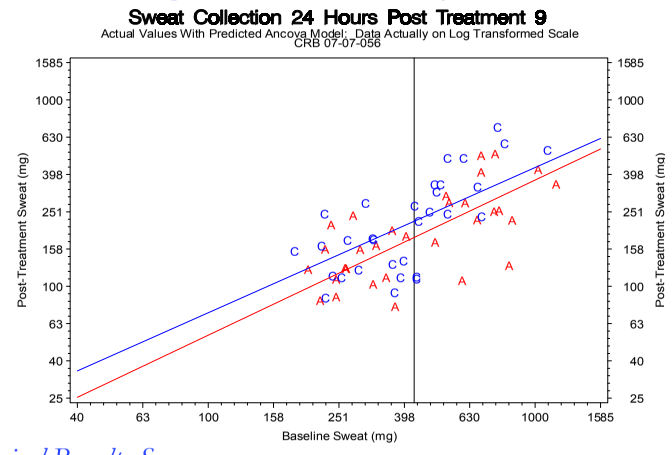


Table 1. *Male Clinical Results Summary*

Treatment		mg sweat Remaining	Difference	Percent Difference	One-sided P-value
A (SS)	Overall	148 mg	50 mg	-34.0%	<0.0001
C (Rx)	Overall	198 mg			
A (SS)	Post-trt 6	155 mg	54 mg	-35.5%	<0.0001
C (Rx)	Post-trt 6	209 mg			
A (SS)	Post-trt 9	141 mg	47 mg	-33.0%	<0.0001
C (Rx)	Post-trt 9	188 mg			

The best estimates are based on combined data from the two studies via meta analysis. A significant benefit (33-35%) for the OTC soft solid was seen as compared to the prescription at both sweat collections.

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.

Figure 4. Female Reduction Averages

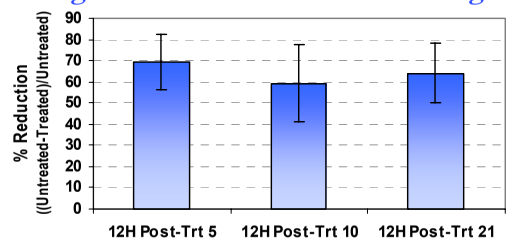
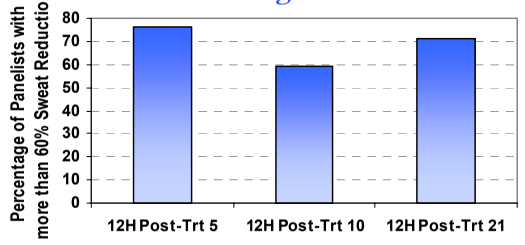


Figure 5.



CONCLUSIONS

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

- **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

1. Thomas M, Kelly Smalls L, Leazer T, Finn E, Elstun L, Hartwig P, Swaile D, Capretta A, Alternative Topical Treatment to an Aluminum Chloride Antiperspirant that Provides Prescription Strength Efficacy with Significantly Less Irritation American Academy of Dermatologists Annual Meeting, 2007.
2. Swaile DF, Chabi GH, Putman CM. Clinical Comparison of Antiperspirant Efficacy as a Function of Morning and/or Nighttime Application. American Academy of Dermatologists Annual Meeting, 2005.
3. Cowan-Ellsberry C, McNamee PM and Leazer T. Axilla Surface Area for Males and Females: Measured Distribution, Regulatory Toxicology & Pharmacology, accepted for publication.

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