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CLINICAL EVALUATION OF TOLERANCE AND EFFICACY OF A NON-RINSED SPRAY USED BY SUBJECT WITH SEBORRHEIC DERMATITIS ON SCALP

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INTRODUCTION & OBJECTIVES

- A new spray containing an antifungal combination of Piroctone Olamine/Cyclopirox Olamine and soothing active ingredients was developed to treat Scalp Seborrheic Dermatitis (SSD) and relieved the undesirable discomfort sensations of the scalp.
- The objective of the clinical study is to evaluate the tolerance and the effectiveness of the new non-rinsed spray on moderate to severe dandruff scalp with intense itching and sensation of burning.

MATERIALS & METHODS

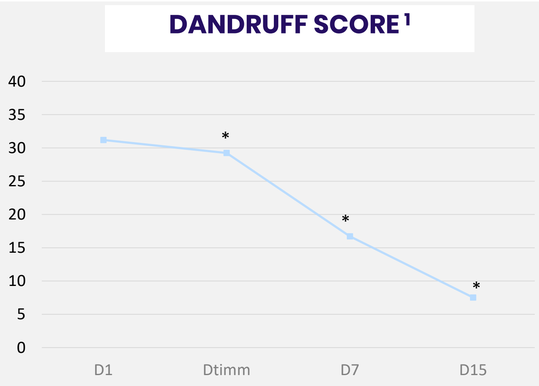
This study was conducted in teenager and adult subjects having mild to moderate recurrent squamous states (SD) associated to erythema assessed by dermatologist and pruritus and burning sensations assessed by subject according to a Numerical Rating Scale (0-10). The new spray was applied thrice a week on dry scalp areas concerned. Subjects used the same neutral shampoo for hair washing. Tolerance and efficacy were assessed after the first application, after 1 and 2 weeks of use depending on the criterion. The efficacy evaluation included scoring of the squamous state, and erythema, self-assessment of burning sensation and cosmetic acceptability.

RESULTS

31 teenagers and adults were included in this clinical study. Results showed a significant decrease of squamous state and erythema clinical score and a significant decrease of pruritus and burning sensations immediately after the first application, after 1 and 2 weeks (*p<0.01) *versus* baseline. Global tolerance was judged very good by the Dermatologist.

The global score of acceptability cosmetics was excellent, the product soothes the scalp (99% of satisfaction), reduces dandruff (97% satisfaction) reduces scalp discomfort (94% of satisfaction), eases itching (94% of satisfaction) and burning sensations (100% of satisfaction).

DANDRUFF SCORE [1]

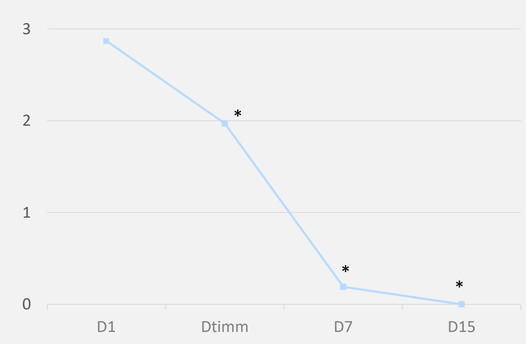


*p<0.01 *versus* baseline

Significant decrease at D1Timm (-6.3%), after D7 (-46.4%) and after D15 (-75.3%) compared to baseline

Spray is effective in reducing squamous status

ERYTHEMA SCORE [2]

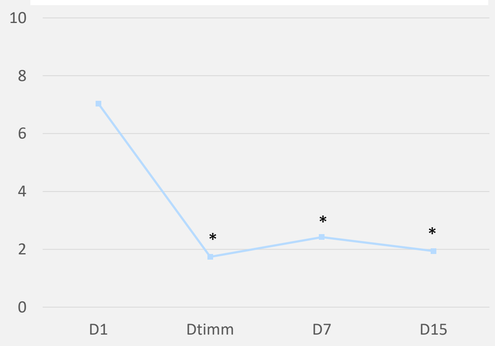


*p<0.01 *versus* baseline

Significant decrease at D1Timm (-31.5%), after D7 (-93.3%) and after D15 (-100%) compared to baseline

Spray is effective in reducing scalp erythema

SUBJECT'S PRURITUS SCORE [3]

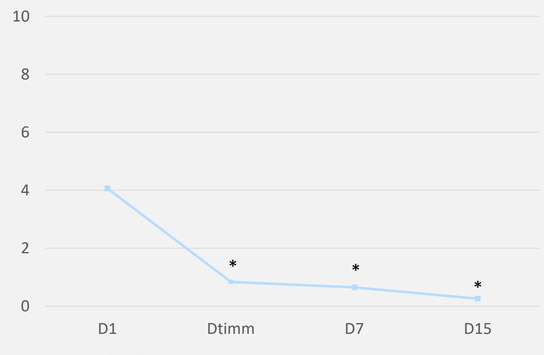


*p<0.01 *versus* baseline

Significant decrease at D1Timm (-75.2%), after D7 (-65.61%) and after D15 (-72.5%) compared to baseline

Spray is effective in reducing scalp pruritus

SUBJECT'S BURNING SCORE [4]



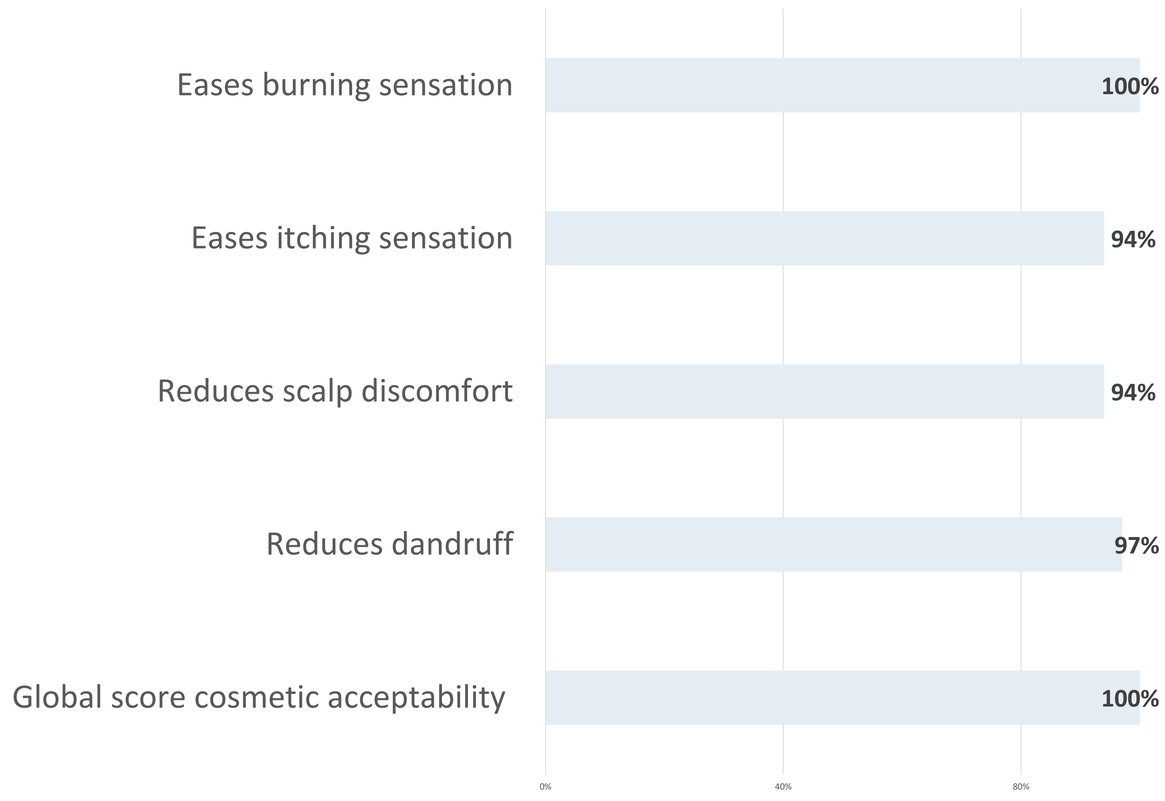
*p<0.01 *versus* baseline

- **Significant decrease at D1Timm (-79.4%), after D7 (-84.1%) and after D15 (-93.7%) compared to baseline**

Spray is effective in reducing scalp burning

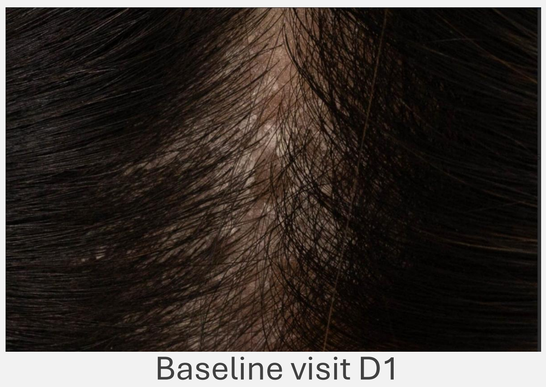
[1]Squire score on a scale of 0 to 80
[2]Erythema score on a scale of 0 to 3
[3]Subject's pruritus score on a scale of 0 to 10 on the laste 3 days
Subject's burning score on a scale of 0 to 3

PRODUCTS AGREEMENT

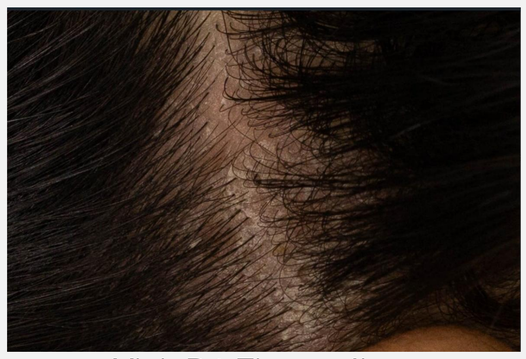


ILLUSTRATIVE PICTURE

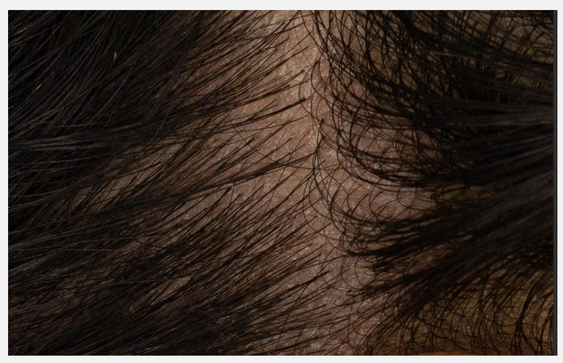
SUBJECT MEAN CASE



Baseline visit D1



Visit D1-Timmediate



End of study - D15

CONCLUSION

The study results' show that the new non-rinsed calming spray displays a very good overall tolerance and confirms the rapid effectiveness at treating scalp seborrheic dermatitis and reduce scalp irritation. Cosmetic qualities and perceived efficacy were highly appreciated by subjects.

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