Efficacy and tolerance of a keratolytic and hydrating shampoo in subjects with mild-to-moderate scalp psoriasis: results from a double-blind, randomized, vehicle-controlled study conducted under real-life conditions

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INTRODUCTION

Psoriasis is a chronic, inflammatory skin disease that affects 2% of the global population.[1]

Scalp psoriasis is estimated to affect up to 80% of patients with psoriasis and can lead to a significant burden and impairment of quality of life (QoL).[2-4]

Due to its chronicity and the poor cosmeticity of topical treatments, compliance to local treatments is a frequent issue in psoriasis.

A keratolytic and hydrating shampoo containing 2% salicylic acid, 5% urea and 1% glycerin acting specifically on psoriasis symptoms has been developed for psoriasis prone scalp.

OBJECTIVE

To assess in subjects with mild-to-moderate scalp psoriasis the efficacy and local tolerance of a keratolytic and hydrating shampoo used under real-life conditions after 30 days.

MATERIAL AND METHODS

Single-center, randomized, double-blind, vehicle-controlled study conducted in 67 adult subjects with mild-to-moderate psoriasis.

- Subjects applied the shampoo daily (2 minutes) from Day 1 to Day 15 and 3 times/week until Day 30.
- Demographic data were assessed at Day 1.
- The Investigator Global Assessment (IGA) and the Psoriasis Scalp Severity Index (PSSI, including erythema, scaling and induration on a 5-point scale each were summed up and weighted by the percentage of the affected area) on 4 defined areas on the scalp, using a dermoscopic device and the total surface affected was calculated for Day 1 pre-wash, Day1 post-wash, Day 8, Day 15 and Day 30.
- Other assessments included hair and scalp greasiness, irritation, subject-assessed SCALPDEX symptoms and product acceptability at Day 1 pre-wash, Day 1 post-wash, Day 8, Day 15 and Day 30.
- The SCALPDEX-based QoL questionnaire was completed at Day 1, Day 15 and Day 30.
- Product acceptability was assessed at Day 15 and Day 30.

References

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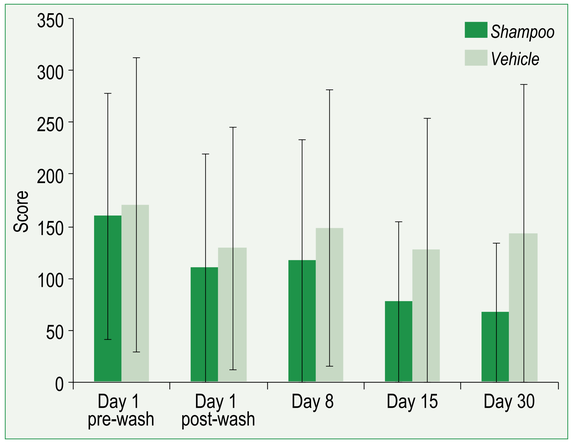
RESULTS

- 67 subjects were included, 65.7% females and 34.3% males. The mean age was 43.2 years. 86.6% had Photoype III. All subjects had sensitive scalp, 58.2% had mild and 41.8% moderate scalp psoriasis.
- The shampoo significantly ($p<0.05$) reduced the PSSI by 39.0%, 37.2%, 63.0% and 69.0% immediately after washing at Day 1 and after 8, 15 and 30 days of use, respectively compared to a 22.8%, 5.5% and 19.6% decrease and 13.0% with the vehicle (Figure 1).
- The symptom, emotion and functioning SCALPDEX items significantly ($p<0.05$) reduced with the shampoo as early as Day 1 post-washing sustaining until Day 30 (Figure 2a to Figure 2c).
- At Day 30, the IGA had significantly ($p<0.001$) decreased with the shampoo by -47.5% and by -6.9% with the vehicle (Figure 3).
- Hair and scalp greasiness, and irritation, significantly ($p<0.05$) improved continuously with the shampoo until Day 30 while it worsened with the vehicle after an initial improvement.
- Subject reported symptom scores paralleled the positive evolution of clinical signs. The desquamation score had decreased by 55.9% (vs 15.8% with the vehicle), the irritation score by 60.8%, the pruritus score by 31.3%, the stinging score by 51.2%, the burning score by 56.6% and the scratching frequency score by 62.6%.
- Figure 4 provides photos showing the improvement of the scalp over time.
- Overall, subject satisfaction was high and QoL had improved; all subjects reported that they would continue using the shampoo.

Figure 1

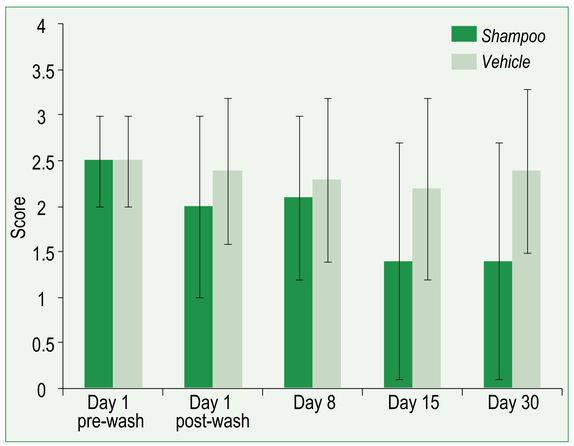
EVOLUTION OF THE PSORIASIS SCALP SEVERITY INDEX OVER TIME



Differences of scores between the shampoo and the vehicle were statistically significant ($p<0.05$) in favour of the shampoo at all post Day 1 pre-wash evaluations.

Figure 3

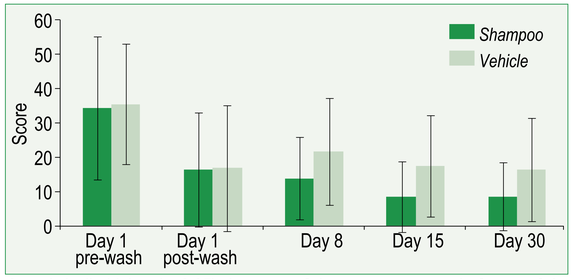
EVOLUTION OVER TIME OF THE INVESTIGATOR GLOBAL ASSESSMENT



The investigators rated the shampoo significantly ($p<0.05$) more beneficial than the vehicle at Day 1 post-wash, Day 15 and Day 30.

Figure 2 a

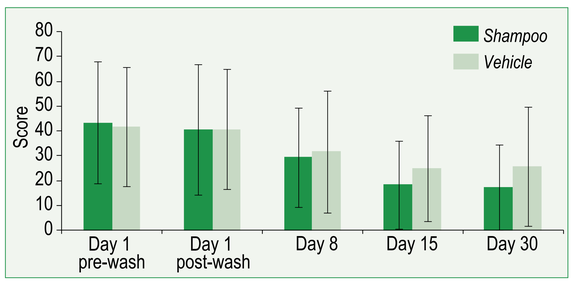
EVOLUTION OF SCALPDEX SCORES OVER TIME



A statistically higher ($p<0.05$) decrease of the symptom score in favour of the shampoo was observed at evaluation Day 15.

Figure 2 b

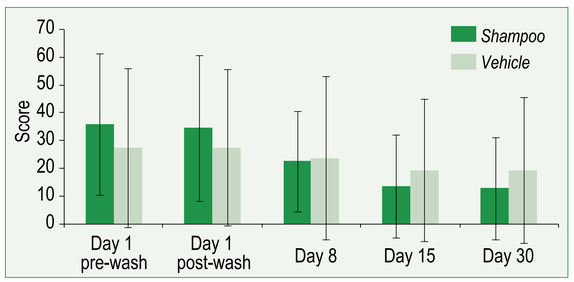
EMOTION SCLAPDEX



A statistically higher ($p<0.05$) decrease of the emotion score in favour of the shampoo was observed at evaluation Day 15 and Day 30.

Figure 2 c

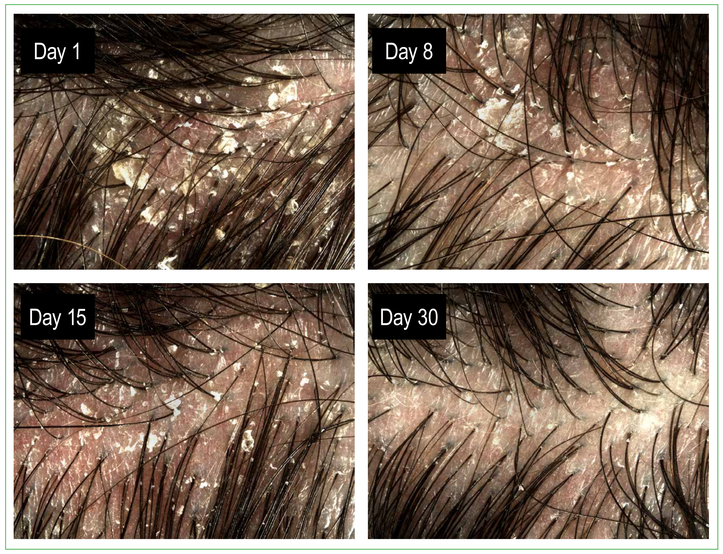
FUNCTIONING SCLAPDEX



A statistically higher ($p<0.05$) decrease of the functioning score in favour of the shampoo was observed at evaluation Day 15 and Day 30.

Figure 4

VISUAL SUPPORT SHOWING THE IMPROVEMENT OF THE SCALP OVER TIME



CONCLUSION

- **The tested shampoo significantly improved clinical signs, symptoms and QOL of mild-to-moderate scalp psoriasis compared to vehicle, with efficacy observed as early as the first day of use, and up to 30 days.**
- **It was well tolerated and highly appreciated by the subjects.**
- **Compliance of use is expected to be good.**

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