

# The benefit of Selenium Disulfide shampoo in subjects of any ethnicity or phototype, with mild-to-moderate dandruff or scalp seborrheic dermatitis: results of a real-life observational study from Morocco

## Abstract

**Introduction:** Dandruff is a mild form of scalp seborrheic dermatitis (SSD). Both are chronic and affect individuals regardless of phototype or hair type, and treatment adherence is often challenging. External factors, including heat, dryness, dust and pollution, alter the skin microbiota, including that of the scalp. Selenium disulfide (SeS<sub>2</sub>) shampoo reduces flaking, itching, irritation and scalp erythema in dandruff and SSD.

This study was conducted in Morocco and evaluated the benefit of SeS<sub>2</sub> shampoo in 425 subjects with dandruff or SSD.

**Materials and methods:** This was an open-label, observational, multicentre study in subjects aged ≥12 years, of any ethnicity, photo- or hair type, with SSD of any severity. Participants received SeS<sub>2</sub> shampoo for 8 weeks. Assessments included clinical signs and symptoms, investigator and subject ratings, as well as tolerance evaluation.

**Results:** After 4 weeks of use, desquamation, erythema, irritation, and involved surface area significantly improved ( $p < 0.0001$ ), with results maintained through to Week 8. Improvements in itching and subjective discomfort were also observed. Investigator satisfaction reached 84.5% at Week 4 and 92.6% at Week 8. Mean subject satisfaction scores were  $7.4 \pm 2.2$  and  $7.8 \pm 2.2$  at Weeks 4 and 8, respectively. At Week 8, 88.0% of subjects reported that they preferred SeS<sub>2</sub> shampoo to their previous treatment, and highly appreciated its cosmetic properties. Local tolerance of SeS<sub>2</sub> shampoo was excellent.

**Conclusion.** SeS<sub>2</sub> shampoo significantly improves forms of SSD in subjects regardless of age, ethnicity, photo or hair type, or cultural conditions, after 8 weeks of regular use.

**Keywords:** dandruff, inclusivity, selenium disulfide, scalp seborrheic dermatitis

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## Introduction

Dandruff is a mild form of scalp seborrheic dermatitis (SSD).<sup>1,2</sup> Both conditions are chronic conditions affecting individuals of all phototypes and hair types, and treatment adherence can be challenging.<sup>3,4</sup> Microbial imbalance, involving not only *M. restricta* overgrowth but also shifts in bacterial load, has been associated with dandruff/SSD.<sup>5-7</sup> In particular, *Cutibacterium* spp. and *Staphylococcus* spp. are the 2 dominant bacterial genera in dandruff and non-dandruff scalp, and an imbalance characterised by higher *Staphylococcus* spp. abundance and lower *Cutibacterium* spp. abundance has been reported in dandruff/SSD.<sup>8-13</sup>

External factors, such as heat, air dryness, dust and pollution, may influence the skin microbiota, including that of the scalp.<sup>14,15</sup> In addition, long-term or frequent covering of the hair and scalp (e.g. veils, caps, hats) for cultural, environmental or personal reasons, as well as frequent use of hair straightening procedures, may potentially impact the scalp microbiota by increasing temperature, sebum production or chemical exposure, thereby favouring dysbiosis and *M. restricta* overgrowth. In Arabian countries, natural products such as henna and green clay are frequently used for dandruff management, but their impact on the scalp microbiome is unclear and potential

adverse effects - including contact allergy and immediate-type hypersensitivity reactions after the use of henna - may limit their use.<sup>16,17</sup>

To date, pharmacologically active antifungals and topical corticosteroids remain the mainstay treatments for moderate to severe dandruff and SSD.<sup>18</sup> Several dermatocosmetic antifungal shampoos have shown efficacy in helping to rebalance the scalp microbiome.<sup>19-21</sup>

Selenium disulfide (SeS<sub>2</sub>) shampoo containing salicylic acid, tocopherol and ceramides is beneficial in both dandruff and SSD.<sup>22-26</sup> SeS<sub>2</sub> shampoo reduces flaking, itching, irritation and scalp erythema, and has been shown to be as effective as ketoconazole in dandruff/SSD.<sup>23,27-29</sup> Recently, it demonstrated clinical benefit in SSD subjects across all phototypes and hair types.<sup>30</sup>

The aim of the present observational real-life study was to assess the benefit of SeS<sub>2</sub> shampoo in subjects of any ethnicity or phototype from Morocco presenting with dandruff or SSD of any severity, in routine clinical practice.

## Material and methods

This open-label, observational, multicentre study was conducted in Morocco between September 2022 and April 2023. Due to the study

design and the cosmetic status of the tested product, approval from a local ethics committee was not required. Nevertheless, the study was conducted in accordance with local regulatory requirements, and all subjects provided written informed consent prior to enrolment.

Eligible subjects were residents of Morocco, aged  $\geq 12$  years, of any ethnicity, any Fitzpatrick skin phototype (preferably phototype III and above), and any hair type (I = not curly to VIII = very curly, according to De La Mettrie et al.<sup>31</sup> Participants presented with dandruff or SSD of any severity. Subjects could be treatment-naïve or previously treated for dandruff/SSD.

At inclusion, all subjects were provided with SeS<sub>2</sub> shampoo and instructed to apply the test product for 8 weeks according to its directions for use on the scalp.

Clinical evaluations were performed at baseline (Week 0), Week 4 and Week 8. Baseline assessments included demographic characteristics. At all visits, desquamation, erythema and irritation were assessed using a 0 = “none” to 5 = “severe” scale, the scalp area concerned was graded from 1  $\leq$  10% to 6  $\geq$  90%, and product tolerance was recorded. Subjects rated irritation on the same 0–5 scale, and assessed how bothered they felt by their condition on a 0 = “not bothered at all” to 5 = “very bothered” scale. Overall efficacy of SeS<sub>2</sub> shampoo was assessed by investigators at Weeks 4 and 8 on a 5-point scale ranging from 0 = “worse” to 4 = “very clearly improved”. Overall subject satisfaction was evaluated at Weeks 4 and 8, and product acceptability and cosmeticity were rated at Week 8 on a 0 = “agree not at all” to 10 = “completely agree” scale.

Qualitative variables were summarised as numbers and percentages of each response category, and 95% confidence intervals were calculated where applicable. Quantitative variables were summarised as counts, means, standard deviations, median, minimum, maximum and missing values. All statistical analyses were performed at a 5% significance level using two-sided tests, except for normality testing using the Shapiro–Wilk test at a 1% threshold. Statistical analyses were performed using SAS software (version 9.4, SAS Institute Inc., Cary, NC, USA).

## Results

A total of 477 subjects were enrolled. Data from 425 subjects were included in the statistical analysis; 51 subjects had no follow-up visit with analysable data, and one subject reported no baseline symptoms.

Demographic characteristics are shown in Table 1, and baseline disease characteristics in Table 2. Overall, 53.2% of subjects were female and the mean age was 30.4  $\pm$  11.9 years (range: 18–88 years). Most subjects had Fitzpatrick phototype III (40.1%) or IV (42.6%); 80.8% identified as African, 15.6% as Caucasian, 2.6% as Afro-American and 1.0% as Hispanic. The majority had hair type II (18.8%), III (28.0%) or IV (25.6%). Dandruff was reported in 26.7% of subjects and SSD in 73.3%; both conditions were mainly moderate (dandruff: 48.8%; SSD: 41.7%).

**Table 1** Demographic data

	Total (N=425)
Mean (+/-SD)	30.4 (+/-11.9)
Min ; Max	13.0 ; 88.0
Median	28
Q1 ; Q3	23.0 ; 35.0
Missing	9 (2.1%)

**Table 1** Continued...

<b>Gender</b>	Male	199 (46.8%)
	Female	226 (53.2%)
	I	4 (1.0%)
<b>Phototype</b>	II	34 (8.6%)
	III	158 (40.1%)
	IV	168 (42.6%)
	V	29 (7.4%)
	VI	1 (0.3%)
	Missing	31 (7.3%)
<b>Ethnicity</b>	Caucasian	61 (15.6%)
	Hispanic	4 (1.0%)
	Afro-American	10 (2.6%)
	African	316 (80.8%)
	Missing	34 (8.0%)
<b>Hair type</b>	I	24 (5.8%)
	II	78 (18.8%)
	III	116 (28.0%)
	IV	106 (25.6%)
	V	47 (11.4%)
	VI	20 (4.8%)
	VII	18 (4.3%)
	VIII	5 (1.2%)
	Missing	11 (2.6%)
<b>Relevant specific habit</b>	No	34 (14.4%)
	Yes	202 (85.6%)
	Missing	189 (44.5%)
	Veil	103
	Hat	72
	Hair straightening	61
	Other	6
<b>Previous medical care</b>	Yes	210 (49.4%)
	Topical corticosteroids	112
	Salicylic acid	42
	Ciclopirox	43
<b>Previous dermocosmetic care</b>	Ketoconazole	93
	Yes	324 (76.2%)
	Zinc pyrithione shampoo	108

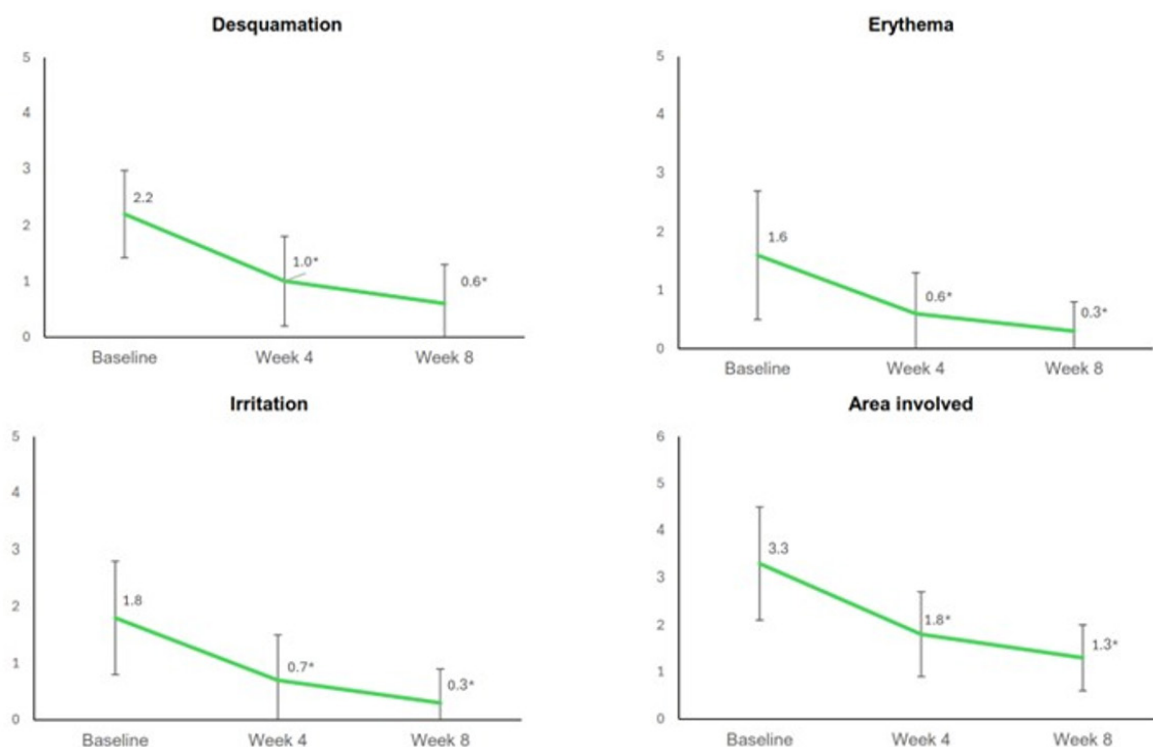
**Table 2** Dandruff and seborrheic dermatitis and other scalp and hair disease data at Baseline

Dandruff (n=425)	Total
Absent	55 (13.0%)
Mild	64 (15.1%)
Moderate	207 (48.8%)
Severe	98 (23.1%)
Missing	1 (0.2%)
<b>Seborrheic dermatitis (n=425)</b>	<b>Total</b>
Absent	113 (26.7%)
Mild	60 (14.2%)
Moderate	177 (41.7%)
Severe	74 (17.5%)
Missing	1 (0.2%)
<b>Other scalp and hair disease data (n=269)</b>	
Androgenetic alopecia	131 (48.7%)
Effluvium telogen	73 (27.1%)
Hair breakage	75 (27.9%)

Overall, 85.6% reported relevant hair habits including hair straightening (77.2%), wearing a veil (57.2%) or wearing a hat (40.0%). Previous treatment for dandruff/SSD was reported by 49.4%. Among them, 54.6% used topical corticosteroids, 45.4% ketoconazole, 21.0% ciclopirox or salicylic acid. Pyrithione zinc shampoos were the most frequently used dermocosmetic products (33.3%).

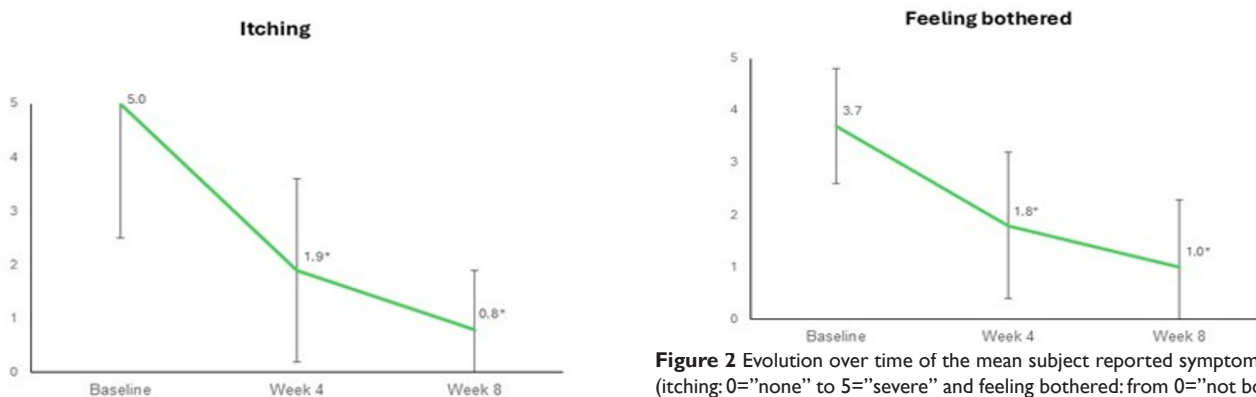
A large majority (95.1%) of subjects used SeS<sub>2</sub> shampoo twice weekly, and 22.3% alternated shampoos. SeS<sub>2</sub> shampoo was used as monotherapy in 46.9% of subjects and as an adjuvant in 42.3%, mainly to corticosteroids (56.5%), ketoconazole (47.6%), ciclopirox (22.4%) or salicylic acid (21.8%). In total, 74.7% maintained their previous treatment while adding SeS<sub>2</sub> shampoo. At baseline, clinical signs were mostly mild or moderate, the mean involved area score was 3.3±1.2, mean itching score was 5.5±2.5 and mean “bothered” score was 3.7±1.1.

According to investigators, dandruff/SSD improved in 93.7% of subjects after 4 weeks, and in 92.6% after 8 weeks of SeS<sub>2</sub> shampoo use. Desquamation, erythema and irritation significantly improved ( $p<0.0001$ ) in 80.7%, 70.2% and 77.1% of subjects at Week 4, respectively. Improvement continued to Week 8 (desquamation: 92.9%; erythema: 81.8%; irritation: 87.0%). The area concerned significantly decreased in the majority of subjects at Week 4 (84.5%) and Week 8 (92.5%). Evolution over time of all clinical parameters is shown in Figure 1. Itching and “feeling bothered” scores also significantly decreased ( $p<0.0001$ ) in most subjects at Week 4 (itching: 90.2%; bothered: 82.0%) and Week 8 (itching: 95.3%; bothered: 89.6%) (Figure 2).



**Figure 1** Evolution over time of the mean clinical sign scores (0="none" to 5="severe") between Baseline and Week 8.

\*:  $p<0.0001$  from Baseline.



**Figure 2** Evolution over time of the mean subject reported symptom scores (itching: 0="none" to 5="severe" and feeling bothered: from 0="not bothered at all" to 5="very bothered") between Baseline and Week 8.

\*:  $p<0.0001$  from Baseline.

Global investigator satisfaction was 84.5% at Week 4 and 92.6% at Week 8; investigators reported that they would replace their currently prescribed treatment by SeS<sub>2</sub> shampoo in 79.1% of cases.

Mean subject satisfaction scores (0–10 scale) were 7.4±2.2 at Week 4 and 7.8±2.2 at Week 8. At Week 8, 88.0% preferred SeS<sub>2</sub> shampoo over their previous treatment, 79.3% judged it more effective, 93.3% wished to continue using it, 88.7% appreciated its cosmeticity and 85.1% reported that their hair looked more natural.

Local tolerance was rated excellent in 97.3% of subjects.

## Discussion

While currently published studies report data including subjects from North Africa, almost all published studies were conducted in European or North American countries. To our knowledge, this is the first study that specifically evaluated the benefit of an anti-dandruff/anti-seborrheic dermatitis shampoo in subjects of any ethnicity or phototype living in a North African country.

Given the climatic, cultural and hygienic behavior differences that may influence scalp microbiota (e.g. higher UV exposure, dust, environmental particulates and specific grooming habits, wearing a veil,...), this study confirms that SeS<sub>2</sub> shampoo significantly ( $p<0.0001$ ) improves dandruff and SSD when used 2–3 times per week for 8 weeks, whether used as initial therapy, replacement therapy or as an adjunctive to pharmacologically active treatments. Improvement was observed regardless of ethnicity, phototype or hair type.

Currently, no data exist regarding the potential impact of more or less occlusive head coverings combined with heat, sweat and sebum production on scalp microbiome composition. This study did not evaluate this aspect, but the findings suggest that adding SeS<sub>2</sub> shampoo or replacing previously used products by SeS<sub>2</sub> shampoo may contribute to improved outcomes, as shown by the 74.7% of subjects who continued their existing treatment while adding SeS<sub>2</sub> shampoo.

High investigator satisfaction (>80%) together with high consumer satisfaction (almost 80%) and the very high preference for SeS<sub>2</sub> shampoo over previously used products (88.0%), combined with excellent tolerance, support SeS<sub>2</sub> shampoo as an effective and well-tolerated therapeutic option for dandruff and SSD in subjects living in North Africa, confirming its inclusivity and benefit across diverse phenotypes.

The observational design did not allow a comparison with other dermocosmetic shampoos in a randomised clinical trial; however, given the large number of products commercially available, this would have been difficult to implement. In addition, assessing microbiome composition in relation to head covering habits, as performed in a recent French study, would require dedicated equipment and logistics beyond the scope of this real-life setting, but represents an interesting avenue for future research.<sup>30</sup>

In 2008, the World Health Organisation recommended in 2008 that SeS<sub>2</sub> formulations should not be applied to damaged skin as there might be a low risk of systemic absorption and associated toxicity with very rare transient systemic symptoms including tremors, weakness, lethargy, lower abdominal pain, and occasional vomiting.<sup>32</sup> However, recent clinical investigations performed with SeS<sub>2</sub> shampoo did not provide any evidence of safety or toxicity issues in subjects with SD.<sup>23,26,29,30,33</sup>

## Conclusion

In conclusion, this observational, real-life study conducted in 425 subjects living in a North African country shows that SeS<sub>2</sub> shampoo significantly improves forms of scalp seborrheic dermatitis regardless of age, ethnicity, photo- or hair type, as well as cultural conditions after 8 weeks of regular use.

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## Author contributions

All authors participated in the study conduct, recruited patients, validated the data collected and participated in the writing and validation of this publication.

## Ethical statement

This cosmetic and observational study did not require any local ethics committee approval. However, all subjects provided written informed consent prior to inclusion.

## Conflict of interest

The authors have no conflict of interest to disclose.

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