

# A selenium disulfide-based shampoo maintains the benefits of medical treatments in severe dandruff and seborrheic dermatitis

Irina Vladimirova<sup>1</sup>, Danuta Nowicka<sup>2</sup>, Monica Arenbergerova<sup>3</sup>, Martina Part<sup>4</sup>, Kuzma Khobzey<sup>5</sup>, Catherine Delva<sup>6</sup>, Delphine Kerob<sup>7</sup>

<sup>1</sup>State dermatological clinic, Saint Petersburg, Russian Federation, <sup>2</sup>Wroclaw Medical University Department of Dermatology, Venereology and Allergology, Wroclaw, Poland, <sup>3</sup>University Hospital Královské Vinohrady, Prague, Czech Republic, <sup>4</sup>Faculty of Medicine, Department of Dermatology and Venerology, Comenius University in Bratislava, Slovakia, <sup>5</sup>Kyiv Medical University, Khobzey Clinic, Kyiv, Ukraine, <sup>6</sup>Sylia-Stat Lancrenon, Bourg-la-Reine, France, <sup>7</sup>Laboratoires Vichy, Levallois Perret, France

## INTRODUCTION

Dandruff is a milder form of seborrheic dermatitis (SD) and is mainly limited to the scalp. SD is a chronic and relapsing inflammatory condition of the scalp, face and upper chest which associates erythema, squames and itching.<sup>1</sup>

It is estimated that dandruff and SD combined affect half of the adult population worldwide. Different factors, such as sebaceous secretion, over colonization by *Malassezia* spp., individual predisposition, and interactions between these factors may contribute to the pathogenesis.<sup>2,3</sup>

Topical therapies remain the mainstay of treatment for scalp seborrheic dermatitis (SSD). The 2 main classes of treatment for SD are topical corticosteroids and antifungal agents.<sup>4,5</sup> Ketoconazole is a fungistatic agent, which limits *Malassezia restricta*, *M. globosa* and *M. furfur* growth, without inhibiting *S. epidermidis* or *S. aureus*.<sup>6</sup> When ketoconazole treatment is stopped, SD symptoms relapse.<sup>7</sup> Selenium disulfide (SeS<sub>2</sub>) is a recognized ingredient to manage efficiently both dandruff and SD. It reduces flakes, itching, irritation and redness of the scalp while acting against *Malassezia* and *Staphylococcus* species.<sup>8-10</sup>

## RESULTS

Overall, women accounted for 56.3% of the studied population. The subject mean age was 34.1±11.3 years.

Table 1 provides detailed demographic and baseline information.

### DEMOGRAPHIC AND MAINTENANCE BASELINE INFORMATION\*

Table 1	Global population		Population pretreated with Ketoconazole	
	n	%	n	%
<b>Gender</b>				
Female	202	56.3	149	55.2
Male	157	43.7	121	44.8
<b>Age (years)</b>				
Mean±SD	34.1±11.3		33.9±11.3	
< 30 years old	72	20.2	60	22.4
[30 - 40[	145	40.6	105	39.2
>= 40 years old	140	39.2	103	38.4
<b>Flakes (score: 0-5)</b>				
0 (none)	2	0.6	1	0.4
1	74	20.6	50	18.4
2	144	40.0	101	37.1
3	140	8.9	120	44.1
Mean score	2.2±0.8		2.3±0.8	
<b>Erythema (score: 0-5)</b>				
0 (none)	34	9.4	22	8.1
1	125	34.6	87	32
2	140	38.8	112	41.2
3	62	17.2	51	18.8
Mean score	1.6±0.9		1.7±0.9	
<b>Irritation (score: 0-5)</b>				
0 (none)	41	11.4	28	10.3
1	140	39	100	36.9
2	120	33.4	98	36.2
3	58	16.2	45	16.6
Mean score	1.5±0.9		1.6±0.9	
<b>Bothered by condition (score: 0-5)</b>				
0 (not bothered at all)	2	0.6	2	0.7
1	21	5.8	15	5.6
2	52	14.5	36	13.3
3	96	26.7	69	25.6
4	108	30.1	86	31.9
5 (very bothered)	80	22.3	62	23.0
Mean score	3.5±1.2		3.5±1.2	

\*Data available for variables

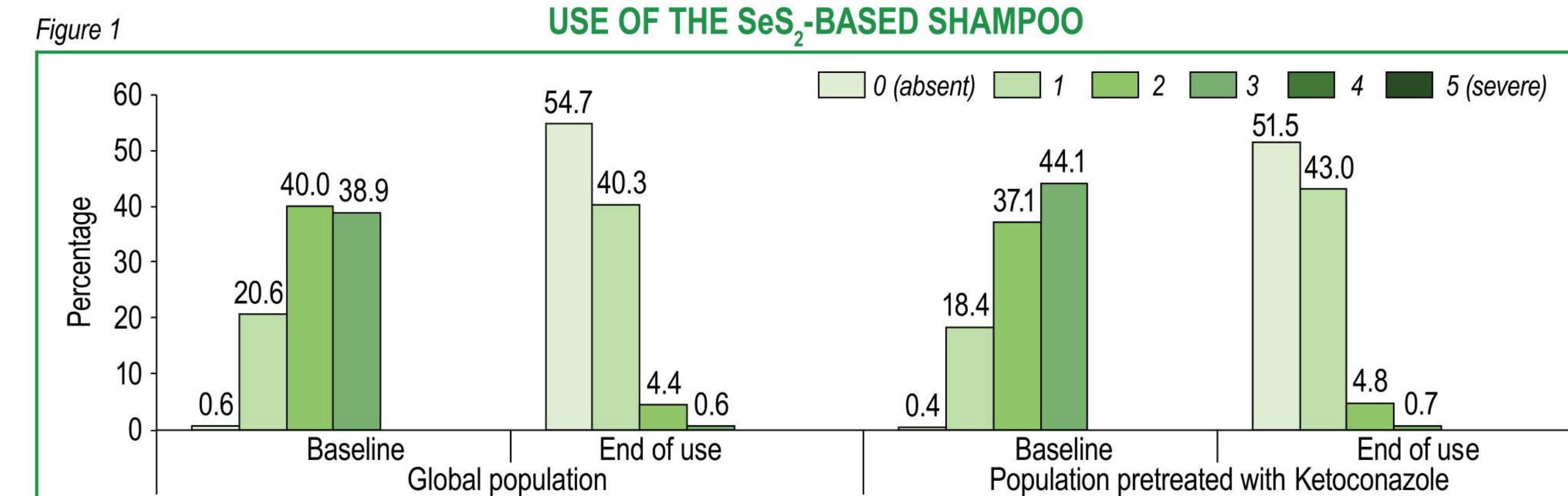
### Global population

At baseline the overall mean score for flakes was 2.2±0.8, for erythema 1.6±0.9 and for irritation 1.5±0.9. At the end of the medicated treatment period, the overall mean score for flakes was 0.5±0.6, for erythema 0.4±0.6 and for irritation 0.3±0.6; 52.5% were still bothered by their condition. 51.7% had their SSD previously treated. Of these subjects; 75.3% used ketoconazole shampoo (KS). Detailed demographic and baseline information is provided in Table 1.

After 6 weeks of use of the SeS<sub>2</sub>-based shampoo, the scalp had further improved in 86.5% (CI95% [83.0;90.1]) of the subjects. Clinical signs had all significantly (p<0.001) improved. Figure 1-3 provide details about distribution of severity of clinical signs at baseline and at the end of the maintenance period. Mean scores at the end of the maintenance phase were 0.5±0.6 for scales, 0.4±0.6 for erythema and 0.3±0.6 for irritation. Significantly less (5.8%, p<0.0001) subjects were still bothered compared to baseline (Figure 4).

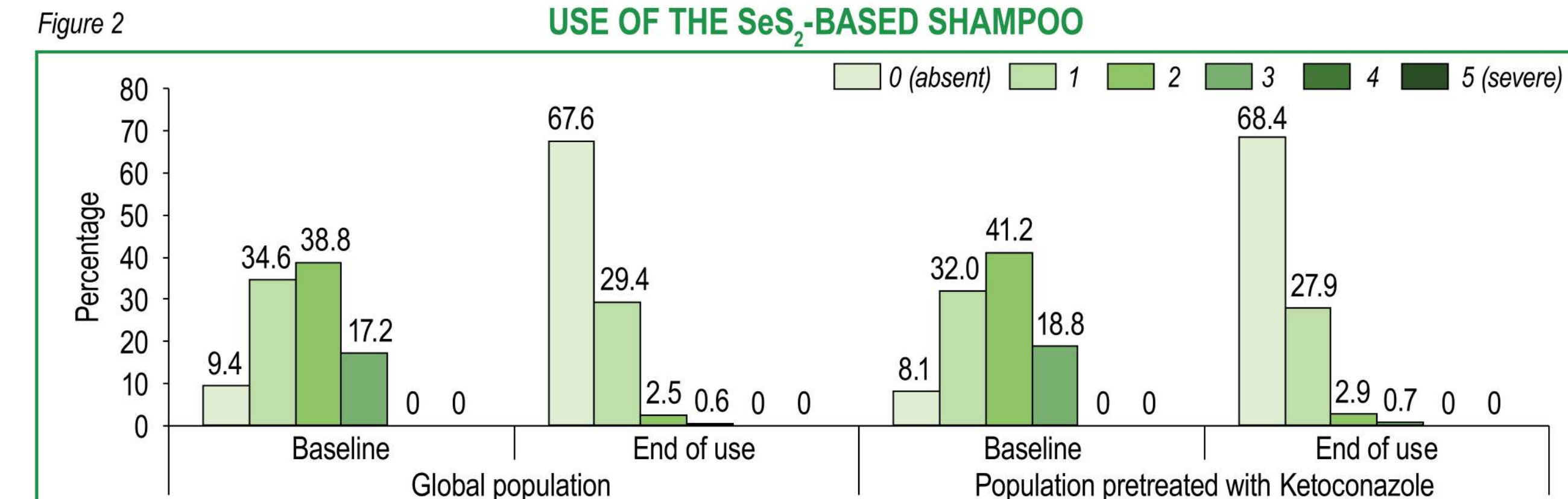
The overall subject satisfaction score was 9.1±1.3 and investigators were satisfied or very satisfied with the treatment outcome in 98.9% (CI95% [97.7;100.0]) of the subjects after 2 months of use. Figure 5 provides details about the satisfaction of the global population with the SeS<sub>2</sub>-based shampoo.

### SEVERITY SHIFT OF FLAKES IN THE GLOBAL POPULATION AND IN THE POPULATION HAVING PREVIOUSLY USED KETOCONAZOLE AT MAINTENANCE BASELINE AND AFTER 2 MONTHS OF USE OF THE SeS<sub>2</sub>-BASED SHAMPOO



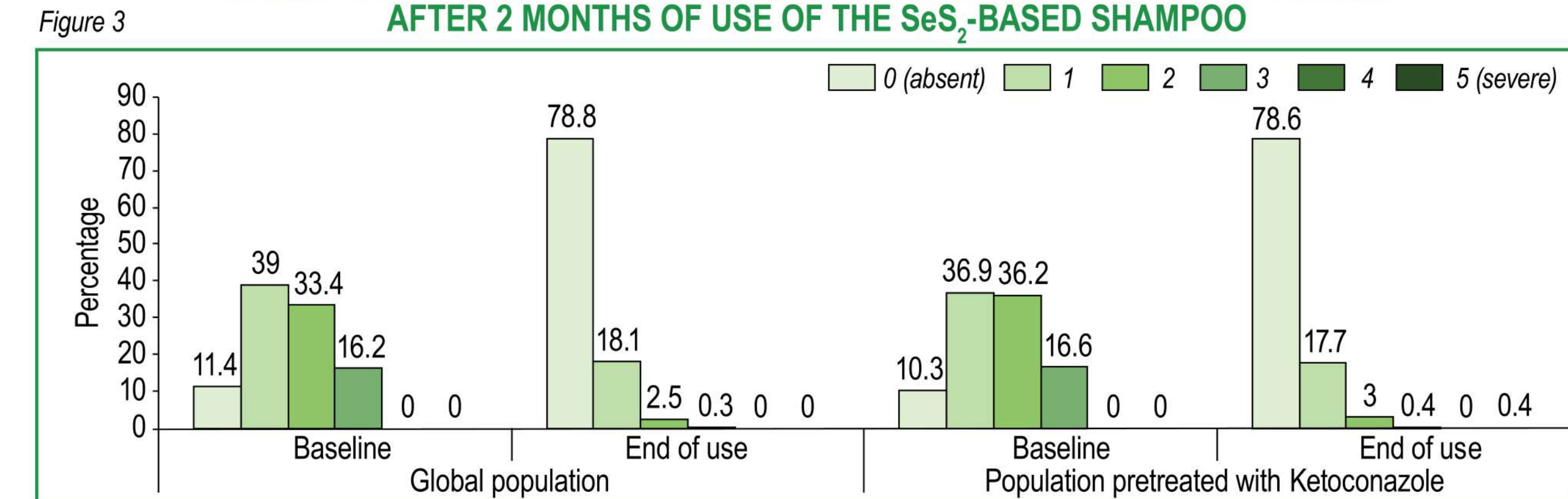
In both populations, improvement was statistically significant (p<0.0001) at the end of the maintenance phase.

### SEVERITY SHIFT OF ERYTHEMA IN THE GLOBAL POPULATION AND IN THE POPULATION HAVING PREVIOUSLY USED KETOCONAZOLE AT MAINTENANCE BASELINE AND AFTER 2 MONTHS OF USE OF THE SeS<sub>2</sub>-BASED SHAMPOO



In both populations, improvement was statistically significant (p<0.0001) at the end of the maintenance phase.

### SEVERITY SHIFT OF IRRITATION IN THE GLOBAL POPULATION AND IN THE POPULATION HAVING PREVIOUSLY USED KETOCONAZOLE AT MAINTENANCE BASELINE AND AFTER 2 MONTHS OF USE OF THE SeS<sub>2</sub>-BASED SHAMPOO



In both populations, improvement was statistically significant (p<0.0001) at the end of the maintenance phase.

## OBJECTIVE

The objective of this observational study was to assess the maintenance effect of a SeS<sub>2</sub>-based shampoo in adults with severe dandruff/SD after an initial medicated treatment.

## MATERIAL AND METHODS

This was an international multicenter observational study conducted in 361 subjects in Eastern Europe who used the SeS<sub>2</sub>-based shampoo after a medical treatment. The SeS<sub>2</sub>-based shampoo was used 2 to 3 times per week for up to 6 weeks.

Efficacy criteria included improvement of scalp, scales, erythema and irritation on a flakes from 0=none to 5=severe and investigator satisfaction. Subjects rated the impact of their SSD (0=none to 5=very bothered), efficacy and satisfaction on a scale from 0=not satisfied to 10=completely satisfied at the end of the study. Tolerance was assessed throughout the study.

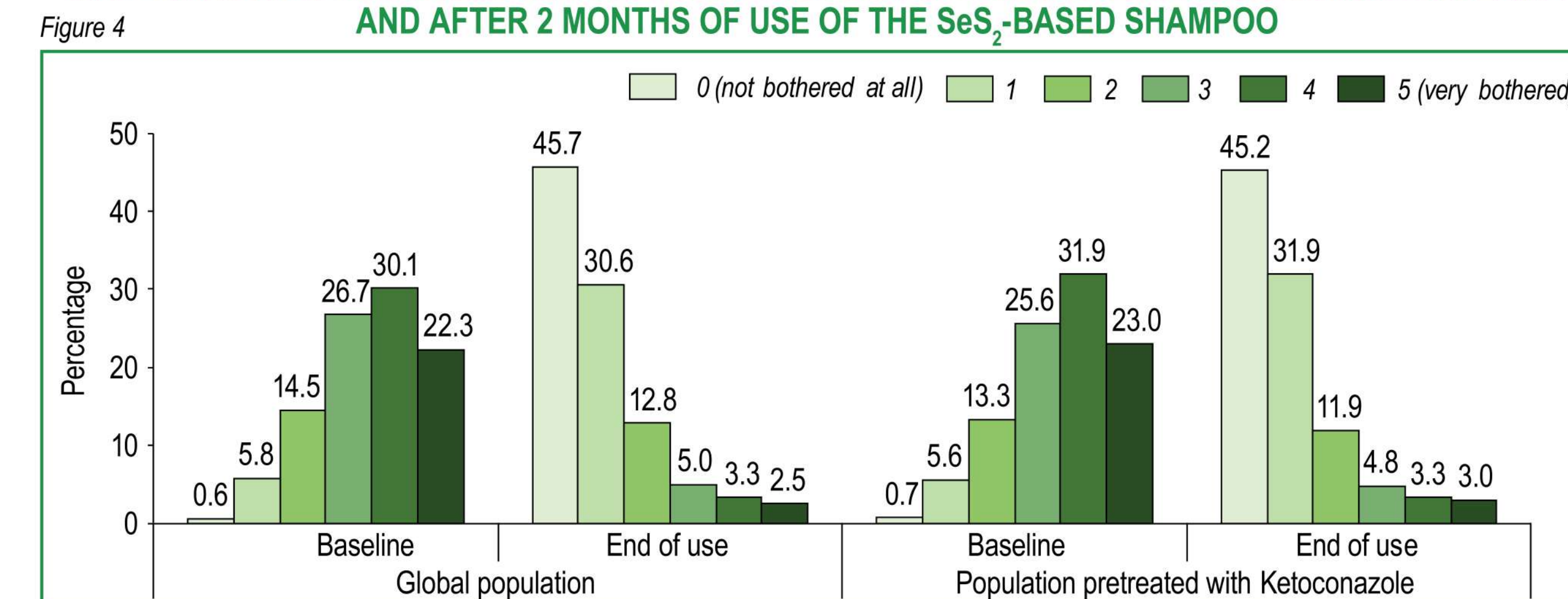
### Population having been pre-treated with ketoconazole

In subjects having been pre-treated with KS, the mean baseline score for flakes was 2.3±0.8, for erythema 1.7±0.9 and for irritation 1.6±0.9; 54.9% were bothered by their condition. After 6 weeks of use of the SeS<sub>2</sub>-based shampoo, the scalp had improved in 86.6% (CI95% [82.5;90.6]). Clinical signs had all significantly (p<0.001) improved with a mean score for flakes of 0.5±0.6, of 0.4±0.6 for erythema and of 0.3±0.6 for irritation at the end of the maintenance period. Figures 1-3 provide detailed results about the evolution of severity of clinical signs at baseline and at the end of the maintenance period.

Significantly less (6.3%, p<0.0001) subjects were still bothered compared to baseline (Figure 4). The overall subject satisfaction score was 9.1±1.3 and investigators were satisfied or very satisfied with the treatment outcome in 99.2% (CI95% [98.2;100.0]) of subjects after 6 weeks of use. Figure 5 provides details about the satisfaction of the population having used previously KS.

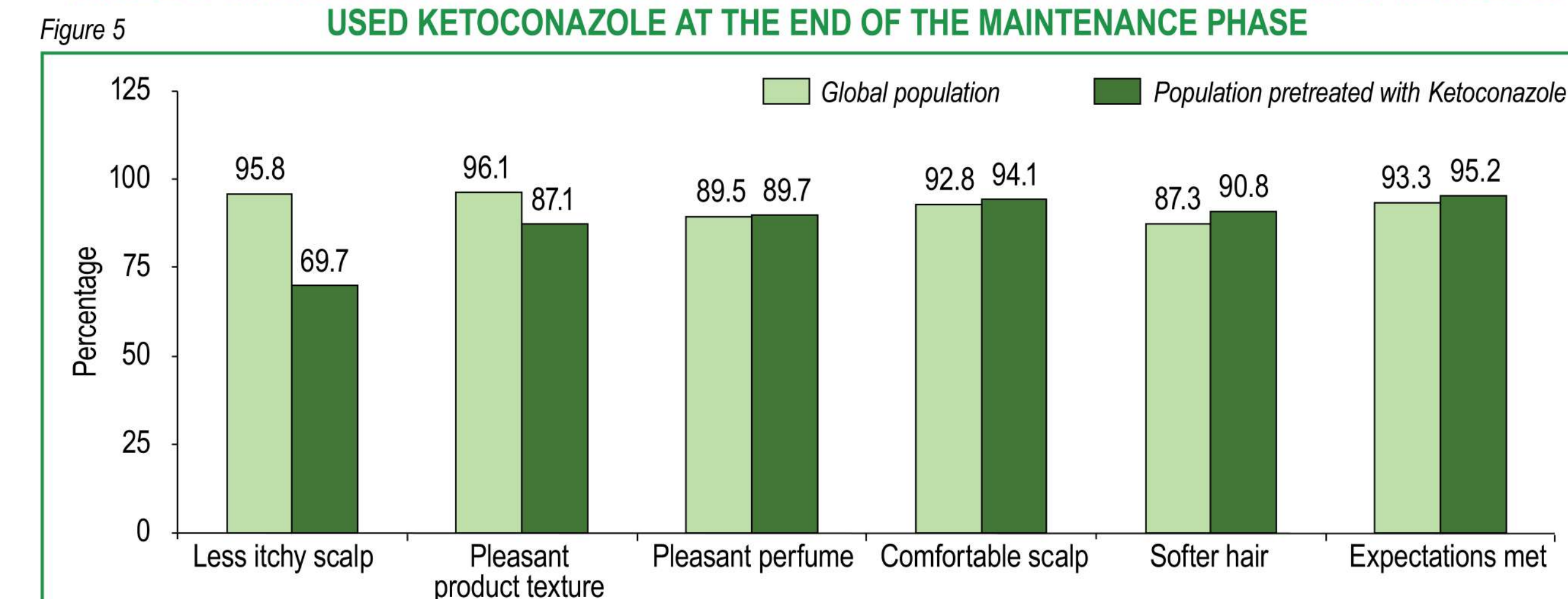
Tolerance was rated good or very good in 99.0% (CI95% [98.4;99.6]) of the subjects.

### PERCENTAGE DISTRIBUTION OF BEING BOTHERED BY THE CONDITION IN THE GLOBAL POPULATION AND ON THE POPULATION HAVING PREVIOUSLY USED KETOCONAZOLE AT MAINTENANCE BASELINE AND AFTER 2 MONTHS OF USE OF THE SeS<sub>2</sub>-BASED SHAMPOO



In both populations, subjects were significantly less bothered significant (p<0.0001) at the end of the maintenance phase.

### PRODUCT APPRECIATION BY THE GLOBAL POPULATION AND THE POPULATION HAVING PREVIOUSLY USED KETOCONAZOLE AT THE END OF THE MAINTENANCE PHASE



## CONCLUSION

The SeS<sub>2</sub>-based shampoo used 2 to 3 weekly efficiently maintains the clinical benefits of medicated treatments including Ketoconazole in severe dandruff/SD. The SeS<sub>2</sub>-based shampoo is very well tolerated.

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## Conflict of interest

Delphine Kerob is an employee of Laboratoires Vichy International, France. The other authors have no conflict of interest to disclose.

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