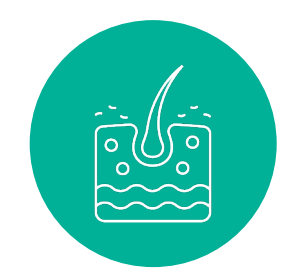


Assessing the Clinical Efficacy, Safety and Tolerance of a Novel Antidandruff Shampoo with Salicylic Acid 3% and Piroctone Olamine 0.75% on Subjects with Dandruff, Dry and Sensitive Scalp: A Nonrandomized Clinical Study

Princy John^{1,2}, Lucie Lasserre², Ricardo Segovia Borray², Tarik Sokolovic², Virginie Nollent², Shiva Patel²

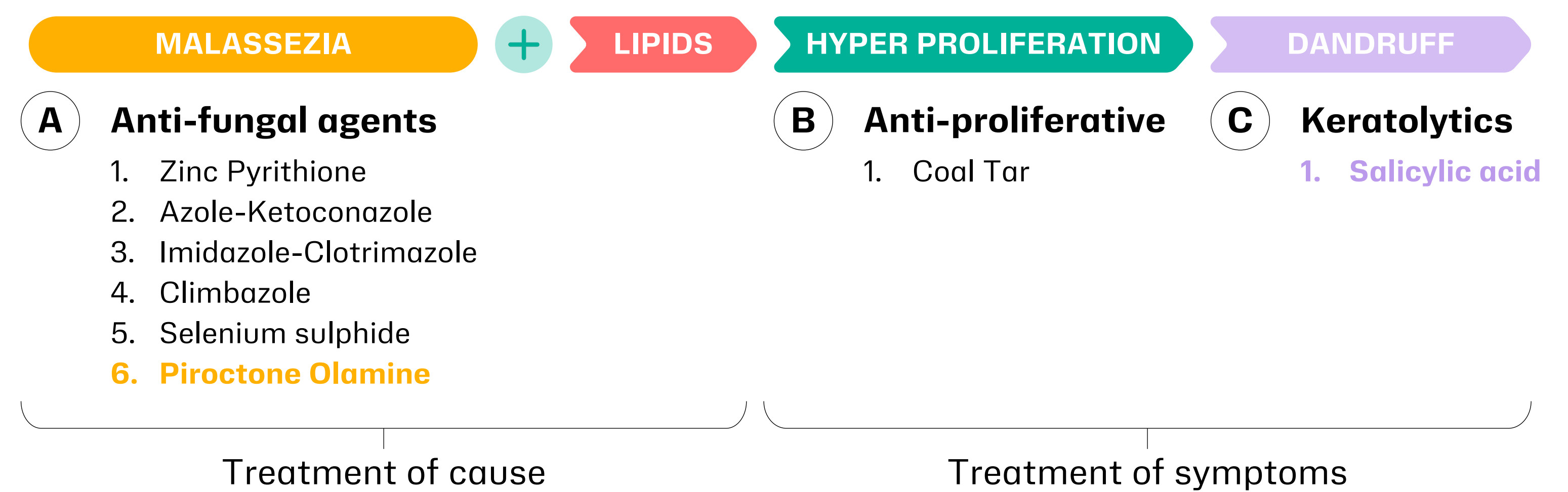
¹Kenvue Brands LLC, regional medical council #: CRM 100578 RQE 38102, São Paulo, Brazil, ²Kenvue Brands LLC, São Paulo, Brazil

Introduction & Objectives



Dandruff is a common condition causing scalp flaking and sometimes itching. Antidandruff shampoos with antifungal agents help manage this condition (Figure 1). Piroctone olamine (PO) targets Malassezia furfur, which contributes to dandruff. Salicylic acid (SA), helps loosen adherent flakes so they are washed away. However, EU regulations limit SA to 3% in rinse-off cosmetic products to avoid excessive dryness. The objective of this clinical study was to evaluate the tolerance and efficacy of a shampoo containing 3% SA and 0.75% PO on dandruff.

Figure 1. Dandruff causes and treatments



Materials & Methods

This clinical study examined the efficacy, safety and tolerance of a combination of antidandruff shampoo on 66 adult participants with dandruff and sensitive, dry scalp. After a two-week washout period using a mild shampoo, participants used the combination shampoo 2-3 times weekly for six weeks. Scalp conditions were assessed at baseline and two follow-ups

(3 and 6 weeks) using various methods: **Self-assessment questionnaires** used a five-point Likert scale, **Dermatological examinations:** cutaneous tolerance for dryness, redness/erythema, and irritation on a scale (0 none to 3 severe), **Clinical grading** assessed overall dandruff quantity and dryness, **Self-grading** measured itching on a 100 mm VAS

scale, **Dandruffmetry** quantified and visually compared flakes.

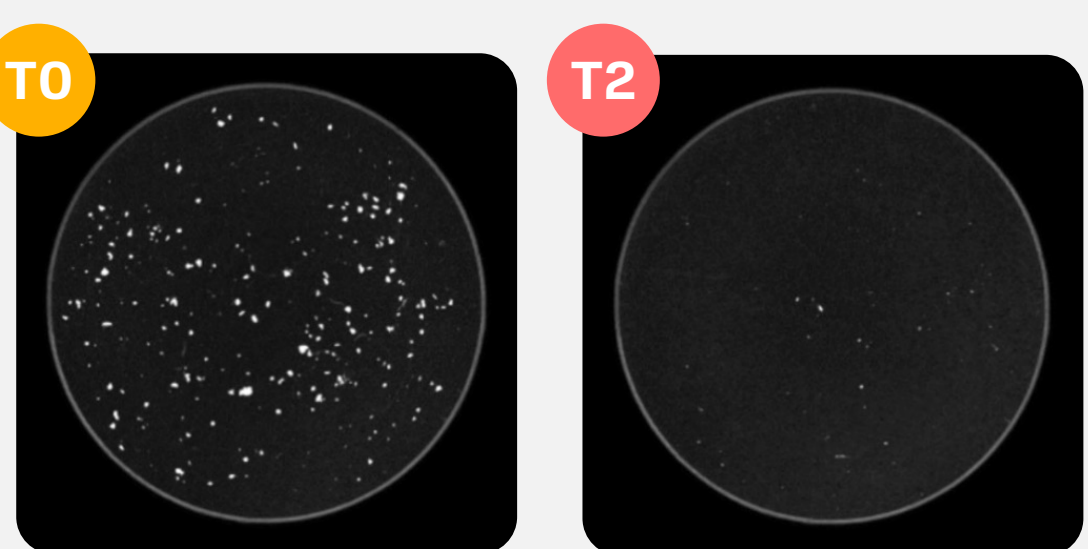
Data were analyzed using SPSS Statistics 27 with non-parametric tests (Sign-Rank and Wilcoxon matched pair tests) to compare follow-up results against baseline. Questionnaire data formed top two boxes (T2B) and bottom two boxes (B2B).

Results

All subjects included in the study had dandruff; 33 (50%) also had sensitive skin/scalp. At baseline, the mean scores for clinically graded dandruff and dryness were 60.8 ± 20.0 and 59.9 ± 19.5 respectively and for overall skin/scalp condition 3.2 ± 1.2 .

The **Self-assessment questionnaire** proved that regular use of the combination shampoo helps to reduce and control visible flakes; relieve itchy scalp and lead to clean hair and scalp (Table 1). There was a statistically significant improvement ($p \leq 0.05$) on follow-up points across all **Dermatological** cutaneous tolerance parameters, **Clinical grading** of dandruff and dryness, and **Dandruffmetry** for area, total count (Fig. 2, Tables 2 and 3). **Self-grading** for itching improved starting after the first use and continued throughout the treatment period. Dermatologist evaluation after 6-week of use showed that 91% of subjects tolerated the shampoo very well. No undesired or pathological and allergic reactions were observed.

Figure 2. Dandruffmetry Petri dish images T0 (Baseline) versus T2 (after 6 weeks regular use)



Subject 1003 representative average results; dandruff was collected from the scalp by combing it out and transferring it to a Petri dish with a dark background. After photographing the Petri dish, the DandruffMeter DA20 software determined the few parameters.

Table 1. Summarizing table of questionnaire at time point 3-week and 6-week

No.	Question	T2B (%)		B@B (%)	
		3-week	6-week	3-week	6-week
1	The product relieves scalp dryness	86.2	4.6	86.2	7.7
2	The product relieves scalp itching	83.1	12.4	86.2	10.8
3	The product prevents scalp dryness	83.1	7.7	78.5	9.2
4	The product prevents scalp itching	81.5	13.8	76.9	16.9
5	The product leaves my scalp feeling clean	90.8	1.5	83.1	7.7
6	The product leaves my scalp looking clean	76.9	6.2	84.6	3.1
7	The product leaves my hair looking clean	84.6	10.8	87.7	7.7
8	The product leaves my hair feeling clean	81.5	7.7	92.3	0.0
9	The product regular use helps to relieve scalp tightness	72.3	10.8	72.3	10.8
10	The product reduces visible flakes	81.5	10.8	80.0	12.3
11	The product helps to control visible flakes	80.0	6.2	94.7	0.0
12	I would recommend this product to fight dandruff	-	-	84.2	10.5

Self-assessment questionnaire results proved that regular use of the IP helps to reduce and control visible flakes; relieve dry, tight, and itchy scalps and leave hair and scalp looking and feeling clean.

5 boxes ("I strongly agree", "I agree", "I neither agree or disagree", "I disagree", "I strongly disagree") to rate product claims. Top Two Boxes (%T2B) – absolutely agree + agree. Bottom Two Boxes (%B2B) – disagree + absolutely disagree.

Table 2. Percent Improvement in Dermatologist Evaluation, Clinical grading and Self grading

Time point	Dermatologist Evaluation				Clinical grading		Self-grading
	Dryness	Redness / Erythema	Rash / Irritation	Overall skin condition	Dandruff	Dryness	Itching
After 1st use	N/A	N/A	N/A	N/A	N/A	N/A	89.4%
3-week	55.4%	66.2%	20.0%	89.2%	95.4%	100.0%	92.3%
6-week	83.1%	76.9%	26.2%	93.8%	100.0%	100.0%	93.8%

After 3 weeks and 6 weeks of application, the parameters Dermatologist evaluation of Dryness, Redness/Erythema, Rash / Irritation and Overall Skin Condition were significantly improved $p < 0.05$.

Self-grading for itching showed continues improvement starting after first use.

Table 3. Dandruffmetry

Time point	Area	Count	Count of flake sizes						
			1-42 Pixel	43-83 Pixel	84-124 Pixel	125-165 Pixel	166-206 Pixel	207-249 Pixel	205+ Pixel
3-week	93.8%	92.2%	89.9%	87.7%	73.8%	60.0%	44.6%	43.1%	38.5%
6-week	100.0%	100.0%	98.5%	93.8%	80.0%	64.6%	47.7%	46.2%	40.0%

The statistical evaluation of the panel data showed significant improvement ($p < 0.05$) on both follow-up points for all the dandruffmetry for area, total count, and counts of all flake size categories.

Conclusion

In conclusion, this novel combination of antidandruff shampoo containing 3% Salicylic acid (SA) and 0.75% Piroctone olamine (PO) starts working from the first use, relieves dryness and itchiness, reduces and prevents visible flakes, has a good tolerance profile and is effective as antidandruff product.