BERACA

BERACARE
ADA SYSTEM

active Performance Systems

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BERACA presents a wide portfolio composed of fixed oils, butters, scrubs, clays and actives sustainably sourced from the Brazilian biodiversity. The ingredients come from extractive communities throughout Brazil and are manufactured to connect our biodiversity with thousands of consumers around the world. Through a relationship marked by transparency, traceability and innovation, Beraca contributes directly to regional development and environmental preservation.

ADA

BERACARE ADA

ANTI - DANDRUFF
ACTIVE SYSTEM

BERACA

GENERAL INFORMATION

Product code: BA34110B**XXX**

COSMETIC USE

Beracare ADA System is a natural complex with presence of beta-caryophyllene and selenium. It has anti-seborrheic action and anti-inflammatory activity, and can be used in products for dry or oily hair with dandruff propensity. We indicate its use in shampoo, conditioner, hair lotion, gels and tonics.

EFFICACY EVALUATION

INTRODUCTION

Seborrheic dermatitis is an inflammatory, scaly, erythematous, acute or chronic disease. It has characteristics of high frequency, chronicity, recurrence and is predominately located in areas where there is greater concentration of sebaceous glands (scalp, face and trunk). It occurs in both sexes, between 18 and 50 years, but predominately in men, whose sebaceous production is greater. It usually begins in adolescence, coinciding with the onset of sebaceous gland functioning. The most common and mild form of the disease is dandruff (Pityriasis capitis).

The cause of seborrheic dermatitis is not decisively established. The existence of a "seborrheic constitution" is admitted and it is possible that it is genetically determined.

In predisposed patients, it can be triggered or exacerbated by certain factors such as: climatic changes (harsh winter), states of nervous tension that increase the microorganisms such as bacteria and fungi on the scalp, fatigue, perspiration, low frequency of hair washing, etc.

Recently a pathogenic role has been attributed to a fungus: Malassezia (also referred to as Pityrosporum), present in the scalp of all humans. They are indicated as the main etiological agent of seborrheic dermatitis, with mechanism still unknown.

The clinical presentation is varied and includes an association of different frames, with varying degrees of severity and severity. It is characterized by erythematous lesions with dry or oily scales and yellowish coloration. It affects the scalp preferentially, being called Pityriasis capitis or dandruff, which is not contagious, having periods of improvement and worsening, with 50% of Brazilians having dandruff at least once a year.

As dandruff has no definitive cure, according to scholars, it can be said that the most desirable property of an anti-dandruff shampoo is the removal and the suppression of dandruff recurrence until the next use of the product. Substances such as selenium sulfate, zinc pyrithione, corticosteroids, ketoconazole and octopirox have good results in the control of dandruff. Their focus is either the reduction of scalp oiliness or the control of fungus growth.

Beraca's Beracare ADA System active is an exclusive complex that contains assets of Copaiba and Brazil nut oils that combine the following properties:

- Presence of bioactives: Beta-caryophyllene and selenium
- Anti-inflammatory activity
- Promotes balance of sebum production without drying the skin

To prove the properties, Beraca investigated the potential of the ADA System for the treatment and care of dry and oily hair with dandruff propensity.

OBJECTIVE

The aim of the study was to evaluate the efficacy of the anti-dandruff treatment with active Beracare ADA System at 2%, through clinical analysis.

METHODS

1. Laboratory

The study was conducted in an independent laboratory, *Kosmoscience Ciência & Tecnologia Cosmética Ltda*. Study reference: BC007-08 - R0.

2. Experimental groups and treatment

Table 1 presents the experimental groups and their respective treatments for this evaluation.

Table 1. Products used in study protocol BC007-08 .

Experimental group	Treatment
PLACEBO	Shampoo without Beracare ADA System
	Conditioner without Beracare ADA System
BERACARE ADA SYSTEM	Shampoo containing Beracare ADA System at 2.0%
	Conditioner containing Beracare ADA System at 2.0%

All products were stored at room temperature for the duration of the study.

3. Methodology

The efficacy evaluation of the study products consisted of the application of shampoo + conditioner treatments with and without the Beracare ADA System used every other day for 2 weeks, totaling 8 treatment applications. The result of each treatment was compared to the initial state prior to the application of the treatment (the Control) in each of the volunteers. For this evaluation, 30 volunteers, aged 36 to 47 years, were randomly divided into two groups: **Placebo** and **Beracare ADA System**. All of them had dandruff during the selection period.

3.1 Clinical efficacy

The most obvious symptom of dandruff is scaling of the scalp. Thus, clinically, the intensity of dandruff was monitored at the beginning and at the end of the study.

In order to evaluate the significance of the reduction of dandruff intensity, promoted by the test products, the values of dandruff Intensity (IC) were statistically compared using the paired bimodal t test with a 95% confidence interval.

3.2 Analysis using images

3.2.1 Collection of dandruff

The hairs of each volunteer were brushed over a chamber with removable black background, and uniform and defined size.

3.2.2 Count of dandruff

The black background, containing the removed dandruff, was digitized using a digital camera (Kodak DX6490) with resolution of 3.1 Megapixels.

For the counting of the Quantity of Dandruff (QC), the binarized image was used, in which the dots are the black dots given in units / mm². The counting, in units / mm² was done using an image analysis software.

In order to evaluate the significance of the reduction of dandruff quantity, promoted by the test products, the values of dandruff quantity (QC) were statistically compared using the paired bimodal t test with a 95% confidence interval.

4. Evaluation by photomicrography

The evaluation by photomicrography was performed through a standard process of obtaining images of the volunteers of the region of the scalp with magnification of 120x. These images illustrate the variation of scalp casts for each test product evaluated.

Figure 1 illustrates the process of obtaining the images.

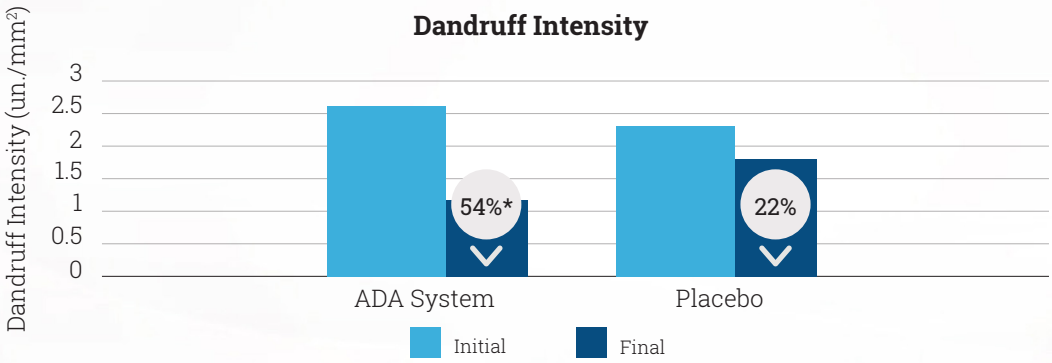
Figure 1. Obtaining the photomicrographs using the Moritex i-Scope camera. The photograph is illustrative and does not present any of the volunteers in this study.

RESULTS

1. Sensory analysis

1.1 Clinical efficacy

Graph 1 shows the means of the values assigned by the volunteers.



* Statistical significance p <0.05 compared to Control.

Graph 1. Mean values of Dandruff Intensity (IC). Results of the in vivo evaluation of the anti-dandruff activity of the Beracare ADA System used at 2% in treatment of 8 application, during 2 weeks.

Thus, the results showed that Beracare ADA System treatment promoted a significantly greater reduction after 2 weeks of use.

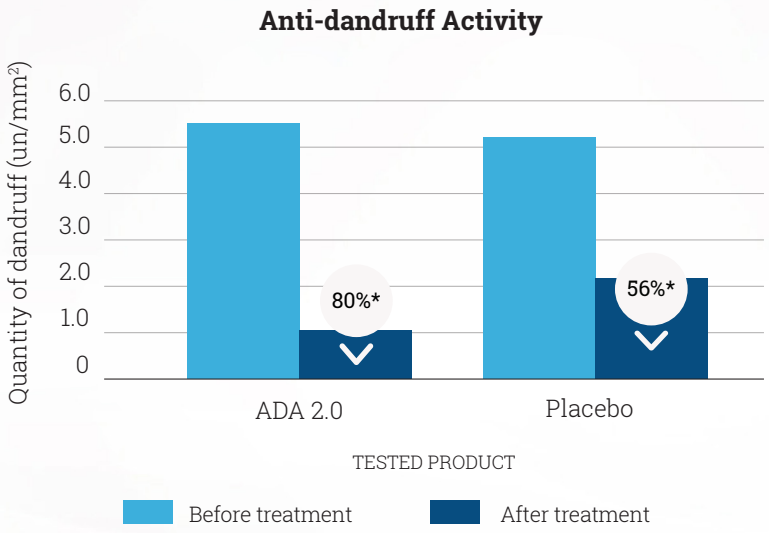
The mean result, shown in Graph 2, indicated a significant reduction of 54% for the treatment with Beracare ADA System compared to **Control** (treatment initiation), reducing the intensity of the dandruff in 100% of the volunteers.

For the **Placebo** group, the mean score indicated a 22% reduction, not significant. The reduction was observed in only 53% of the volunteers.

2. Analysis using images

Figure 2 presents a digitized and binarized image (after image analysis and treatment). Graph 2 shows the mean value at the beginning and at the end of the study.

Figure 2. Scanned image and binarized image for dandruff counting.



* Statistical significance p<0.05 when compared to the condition before treatment.
In vivo evaluation results of anti-dandruff activity of ADA active at 2.0%.
The treatment had 8 applications during 2 weeks.

Graph 2. Results of the in vivo evaluation of the anti-dandruff activity of the Beracare ADA System used at 2.0% in a treatment of 8 applications, during 2 weeks.

Thus, the results show that treatment with Beracare ADA System was effective after 2 weeks of treatment in clinical evaluation after comparison with placebo and control treatments.

The mean result, shown in Figure 3, indicated a significant reduction in the amount of dandruff (QC) of 80% for treatment with **Beracare ADA System** in relation to **Control** (initiation of treatment), reducing the intensity of the dandruff in 100% of the volunteers.

For the **Placebo** group, the mean score indicated a 56% reduction, not significant. The reduction was observed in only 87% of the volunteers.

3. Evaluation by photomicrography

Figure 3 shows the comparison between the test products at the beginning and after the 8 applications over 2 weeks of treatment.

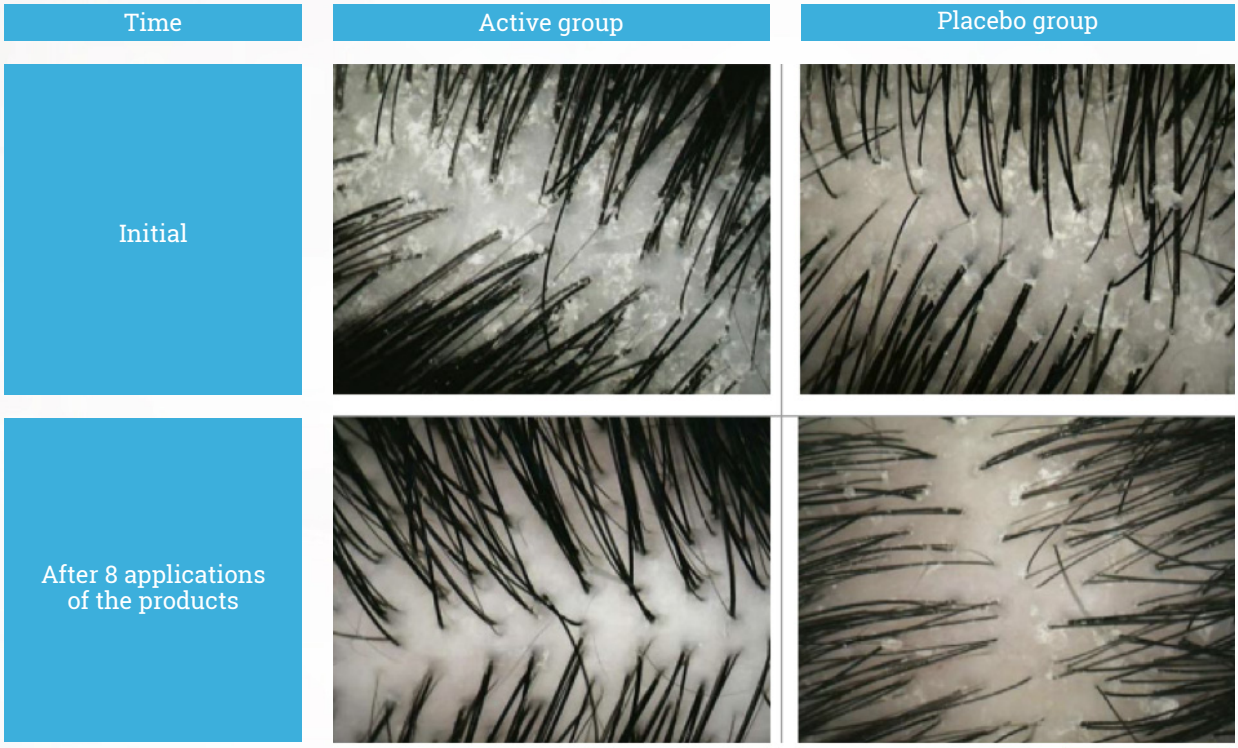


Figure 3. Results of the in vivo evaluation of the anti-dandruff activity of the Beracare ADA System used at 2.0% in a treatment of 8 applications, during 2 weeks, by photomicrographs of two volunteers.

It is observed that after the treatment there was a reduction in the scaling of the scalp, with a considerable improvement after 2 weeks of treatment.

Although the Placebo group also presented reduction of the dandruff, it was observed that for this group there was no significant improvement after treatment.

CONCLUSION

According to the results of sensorial analysis by clinical efficacy, it was possible to verify a significant reduction of the dandruff intensity of approximately 54% in relation to the initial state, and that 100% of the volunteers presented reduction of the intensity of dandruff.

Based on the results of the image analysis, it was possible to observe a significant reduction of approximately 80% in the number of flakes, and that 100% of the participating volunteers had a reduction in the amount of dandruff.

Based on the photomicrograph evaluation, there was a noticeable improvement in the scaling of the scalp after treatment with the active.

In this way, the Beracare ADA System active was effective in decreasing the intensity and amount of dandruff when used at 2.0% in hair treatment, in addition to perceptibly reducing the scalp scaling due to its antiseborrheic action and its anti-inflammatory activity.

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ATTACHMENT

FORMULATIONS USED IN TESTS

PLACEBO SHAMPOO	
INGREDIENTS	**% w/w**
Aqua	Up to 100%
Dissodium EDTA	0.01
Sodium laureth-2 sulfate	28.00
Cocamidopropyl Betaine	6.00
Sodium laureth sulfate (and) glycol diestearate (and) Cocamide MEA	3.00
Cocamide DEA	3.00
Aqua	10.00
Imidazolidinyl Ureia	0.30
Fragrance	0.50

SHAMPOO WITH BERACARE ADA SYSTEM AT 2.0%	
INGREDIENTS	**% w/w**
Aqua	Up to 100%
Dissodium EDTA	0.01
Sodium laureth-2 sulfate	28.00
Cocamidopropyl Betaine	6.00
Sodium laureth sulfate (and) glycol diestearate (and) Cocamide MEA	3.00
Cocamide DEA	3.00
Beracare ADA System	**2.00**
Aqua	10.00
Imidazolidinyl Ureia	0.30
Fragrance	0.50

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PLACEBO CONDITIONER	
INGREDIENTS	**% w/w**
Aqua	Up to 100%
Dissodium EDTA	0.01
Cetrimonium Chloride	3.00
PPG-15 Stearyl Ether	0.80
Steareth-2	0.70
Steareth-21	0.50
Cetearyl Alcohol	3.50
Aqua	10.00
Imidazolidinyl Ureia	0.30
Fragrance	0.50

CONDITIONER WITH BERACARE ADA SYSTEM AT 2.0%	
INGREDIENTS	**% w/w**
Aqua	Up to 100%
Dissodium EDTA	0.01
Cetrimonium Chloride	3.00
PPG-15 Stearyl Ether	0.80
Steareth-2	0.70
Steareth-21	0.50
Cetearyl Alcohol	3.50
Beracare ADA System	**2.00**
Aqua	10.00
Imidazolidinyl Ureia	0.30
Fragrance	0.50

REGULATORY INFORMATION

INCI name (PCPC)	CAS number
COPAIFERA OFFICINALIS (BALSAM COPAIBA) RESIN	8001-61-4
BERTHOLLETIA EXCELSA SEED OIL	356065-50-4
INCI name (COSING)	**CAS number**
COPAIFERA OFFICINALIS RESIN	8001-61-4
BERTHOLLETIA EXCELSA SEED OIL	356065-50-4

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