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HAIR LOSS TREATMENT: EFFICACY STUDY (6 months)



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HAIR LOSS TREATMENT:

EFFICACY STUDY (6 months)

Report nº:	07301-4
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I. EVALUATION STUDY

1. OBJECTIVES

Evaluation of the regenerating effect on the hair of a treatment consisting of the concurrent application of Hair Loss Shampoo and Hair Loss Treatment Tonic, both of which are by the NATUR VITAL.

2. DESIGN OF THE EXPERIMENT

2.1. TYPE OF STUDY

In vivo evaluation using human volunteers

The following were carried out:

- Instrumental test, which allows the results to be quantified objectively. The following techniques were used:
 - Photograph
 - Videophototrichogram
 - Trichogram
- Opinion survey

2.2. DESIGN OF THE EXPERIMENT

Number of panelists: 25, men and women of between 20 and 60 years of age.

2.3. METHODOLOGY

Duration of the study: 6 months

The panelists had their scalps treated for a specific period prior to commencement of the study. This consisted of washing the hair every second day with a shampoo formulated exclusively using surfactants, with no further additives. The objective was to remove all traces of other products from the hair. 24 hours after the third wash, the panelists were examined in the laboratory and the following were carried out:

- General photograph of the scalp. This enables us to observe the evolution of the volume of hair on the head.
- Trichogram. This consists of pulling out a number of hairs and examining the condition of the hair bulbs (roots).
- Microcamera photograph of the pulled hair.
- Microcamera photograph of a section of the scalp. This enables us to observe the evolution of the density and thickness of the hair.
- Wash test (how much hair falls out when washed)
- Pull test (how much hair falls out when brushed)

Each panelist then began treatment by washing with the SHAMPOO under study every second day, and applying the HAIR LOSS TREATMENT daily, preferably at night. On days 45, 90, 135 and 180 of the treatment, the panelists were again examined at the laboratory using the aforementioned tests, and they answered an evaluation survey on the treatment

II. RESULTS

3. RESULTS

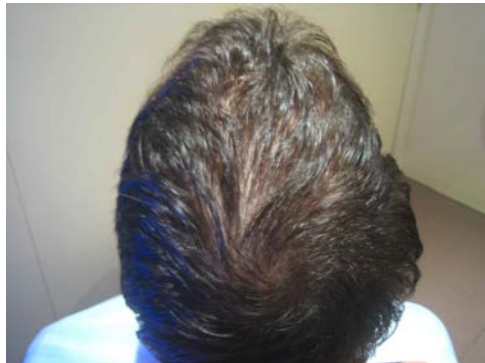
3.1 GENERAL SCALP PHOTOGRAPS



Panelist1

Left: Start of the study (T 0)

Right: End of the study (T 180)



Panelist 10

Left: Start of the study (T 0)

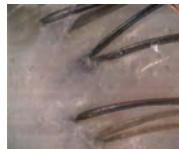
Right: End of the study (T 180)

3.1 OBSERVATION USING MICRO-CAMERA



Panelist 3

Start of the study (T 0) (photographs at x200 magnification)



Panelist 3

End of the study (T 180) (photographs at x200 magnification)



BULB PHOTOGRAPHS

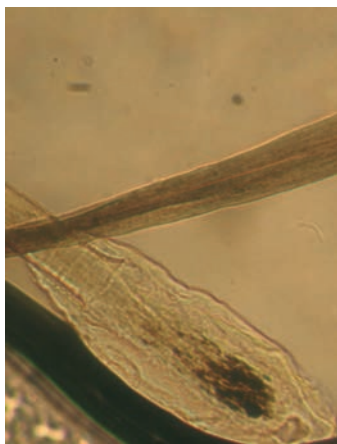


Left: Start of the study (x150)

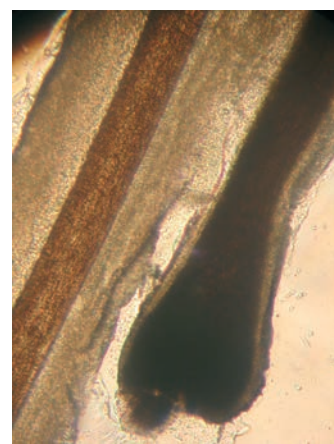


Right: End of the study (x150)

Panelist 7

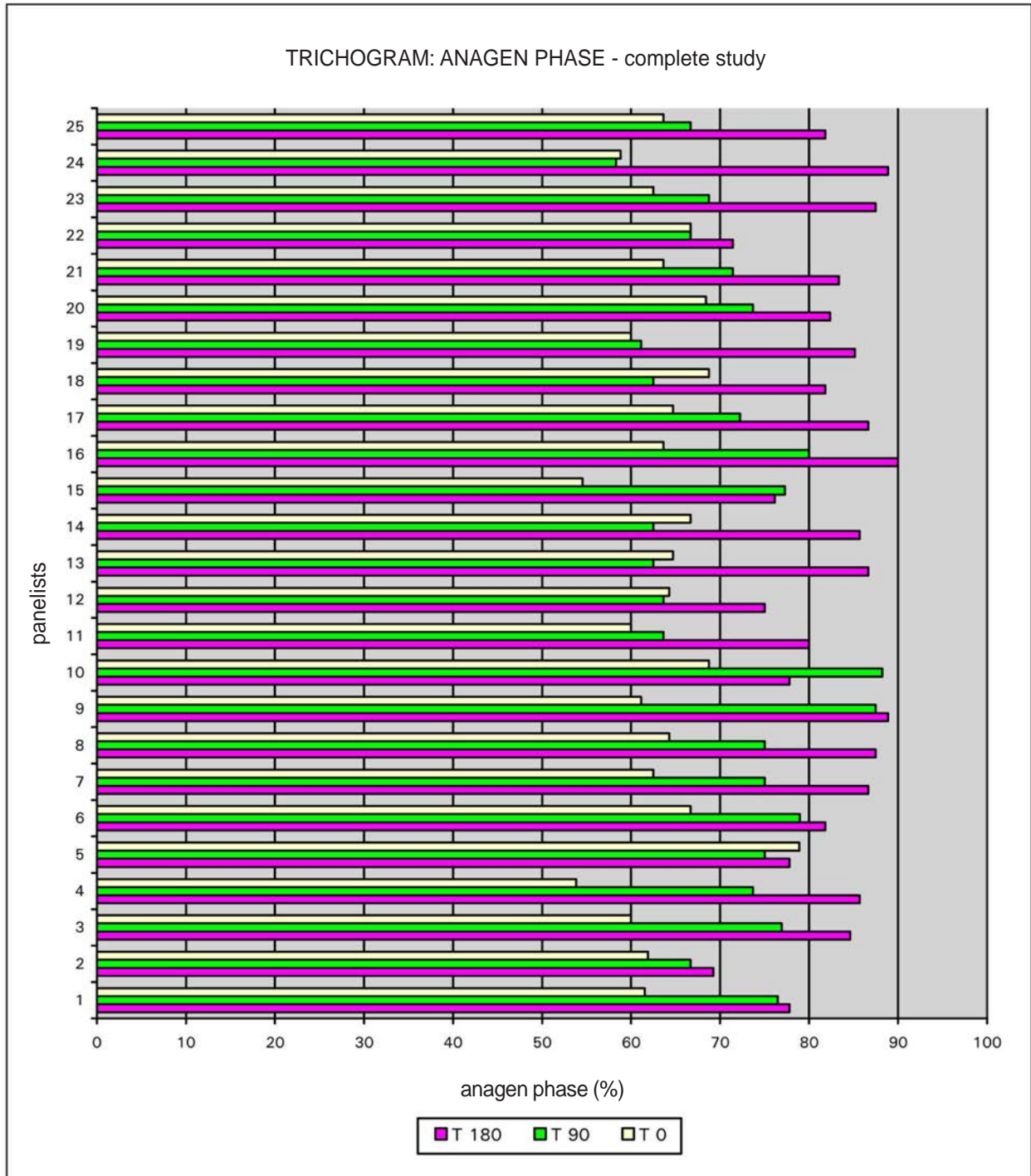


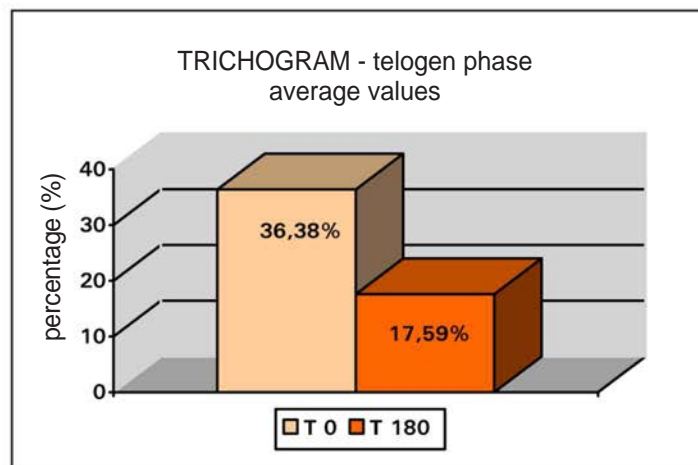
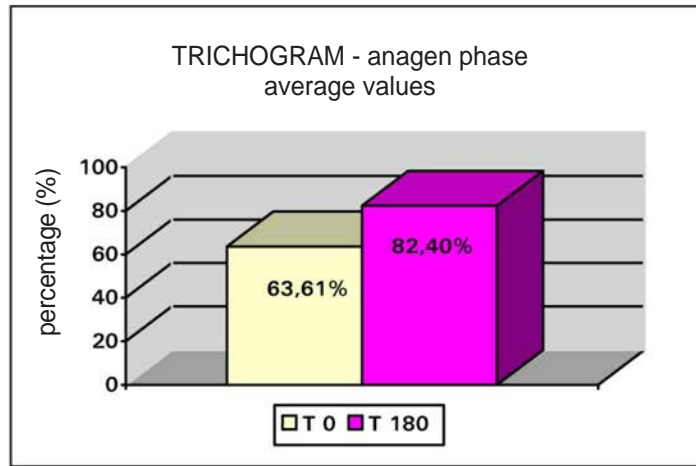
Left: Start of the study (x150)

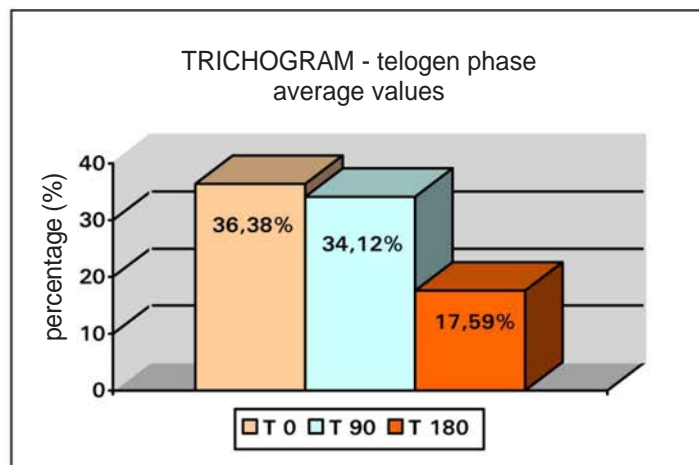
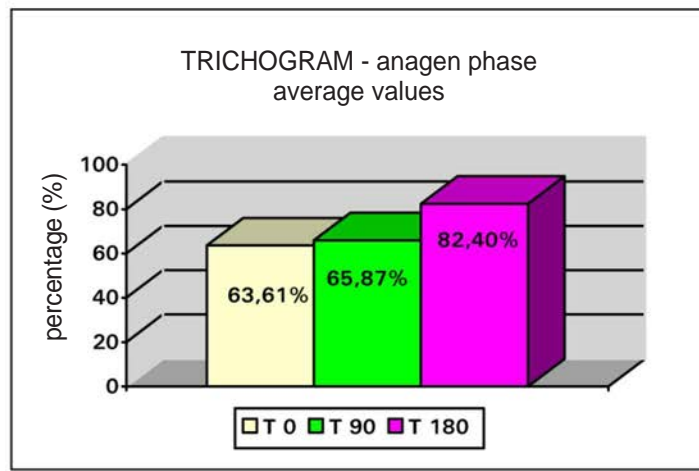


Right: End of the study (x150)

Panelist 10

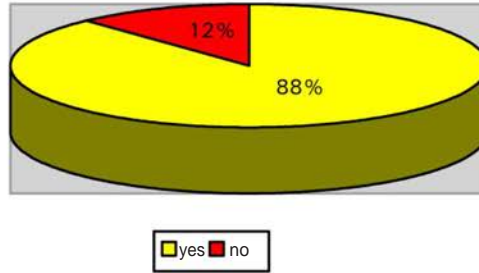




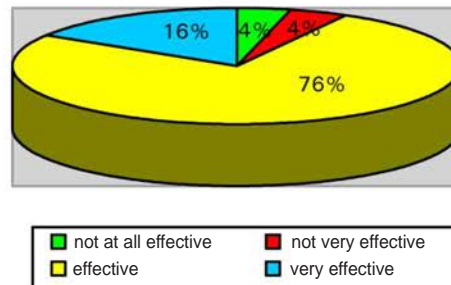




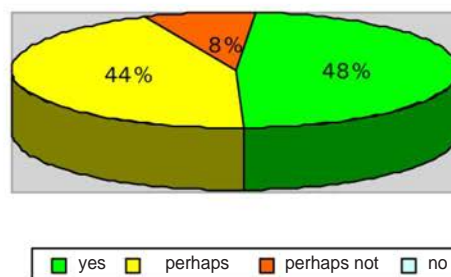
Treatment satisfaction
(T 180)



Treatment efficacy
(T 180)



Treatment purchase intention
(T 180)





III. DISCUSSION

GENERAL SCALP PHOTOGRAPHS

In any study into the efficacy of a hair-regeneration treatment, it is unquestionably preferable for the results to be noticeable to the naked eye. If the treatment significantly increases the number of hairs, general scalp photographs are a simple way to clearly demonstrate the success of the treatment.

The pictures on page 5 show a number of results of the study treatment. The photographs were taken 48 hours after the hair was washed at the start and end of the study.

Panelist 1 demonstrates the efficacy of the treatment. At the start of the study (left-hand photo) the hair at the front is scant, fine and slightly seborrheic as a result of androgenetic alopecia (AGA). At the end of the study (right-hand photo), more hair can be seen at the front, particularly in the middle. All of the scalp hair is less oily and has more body and volume, making it actually look as if there is more hair. The study treatment therefore not only regenerated the hair, as the trichogram examination for Panelist 1 confirmed (see page 8), but the quality and general aspect of the hair also improved substantially, as the panelist himself mentioned in the survey.

The photographs of Panelist 10 provide the next example of the treatment results. In this case, the panelist showed moderate hair loss at the top of the scalp, in particular in the area that coincided with the hair parting, and which was accentuated when it reached the vertex (left-hand photo). By the end of the study (right-hand photo), the amount of hair in this area had grown to completely cover the scalp. The panelist corroborated the efficacy of the treatment in the survey.



OBSERVATION USING MICRO-CAMERA

Scalp photographs obtained from filming with a micro-camera at x150 magnification provided valuable information on hair regeneration. The microphotographs made it possible to ascertain:

- the number of follicular units in a particular scalp area
- the number of hairs that emerged from each follicular unit
- the thickness of the hairs that emerged

Comparing microphotographs of the same scalp area at the start and end of the study revealed whether or not hair regeneration had taken place and to what extent.

The most representative microphotographs for Panelist 3 are found on page 6 of this report. These shots were selected because the shafts of other hairs did not cover the selected area. They also made it possible to observe all the follicle isles in the selected area quite clearly.

A look at the start-of-study and end-of-study photographs of the panelists shows there was generalised growth in the number of follicle isles and the number of hairs in each isle, although growth varied by panelist. Both hair and follicular-isle growth lead to greater hair density, i.e., more growing hairs per surface unit, proving that the hair is regenerating.

The end-of-study microphotographs show hairs of different thickness growing in the same follicular isle. This is completely normal and simply indicates that older hairs coexist alongside new, developing ones.

There was also across-the-board growth in hair thickness. This indicates cell growth of the bulb matrix, which can increase hair diameter.

TRICHOGRAM EXAMINATION

The trichogram results are set out on pages 8 to 10 of this report.

Results halfway through the study (T 90) already hinted at the efficacy of the treatment. In particular, in 18 out of the 25 panelists (72%), an increase of hairs in anagen phase was seen by halfway through the study. In the case of two of them (No. 9 and 15), this growth exceeded 20%.



The end-of-study trichogram results were very satisfactory: 24 out of the 25 panelists (96%) had more hairs in the anagen phase after using the study treatment for six months.

The increase of hairs in the anagen phase at the end of six months (T 180) exceeded 15% for the majority of the panelists and topped 30% in the case of two of them. With regard to the 24 panelists for whom the treatment improved the percentage of hairs in anagen phase, the average increase by T 180 was 19.61%. The average figure for increase of hairs in anagen phase among all 25 panelists was 18.78%.

With respect to the trichogram examination, a large number of hairs broke when removed from the scalp. Breakage usually indicates hair in the anagen phase. Hair in the telogen phase is easy to detect because it comes out easily when pulled and atrophy of the bulb is clearly visible.

Trichogram results can also be analysed by studying the relationship between hairs in the anagen phase and hairs in the telogen phase.

At the start of the study, only seven of the 25 panelists (28%) had a relationship between hairs in the anagen phase and hairs in the telogen phase equal to or greater than 2, and all between 2 and 4.

Halfway through the study (T 90), 19 of the 25 panelists (76%) had a relationship equal to or greater than 2. Of them, 17 (68%) were between 2 and 4. Only two panelists (12%) had a relationship greater than 4.

The results had improved significantly by the end of the study (T 180). All the panelists had a relationship equal to or greater than 2. Eight of them (32%) were between 2 and 4. The majority, i.e., 17 (68%), had a relationship greater than 4.

These figures suggest that the study treatment increased the number of hairs in the anagen phase. This means the treatment was capable of regenerating hair.



BULB PHOTOGRAPHS

Hair bulbs removed for the trichogram examination varied significantly between the start and end of the study.

A look at bulbs in the anagen phase as shown in the photographs on page 7 shows that:

- at the start of the study, the roots were smaller, with cells that were little developed and barely hydrated. The outer sheaths were underdeveloped, looked fibrous and had been compressed from dehydration.
- by the end of the study, the bulbs were well developed and had grown larger. A number of thick, hydrated sheaths were clearly visible, making it easier for the hair to anchor to the structure. Improved anchorage implies increased hair resistance to traction and therefore pulling by combing and would explain why there were more broken hairs when the trichogram examination was done at the end of the study.

PULL TEST (COMBING)

The study results indicated that all panelists experienced a reduction in the number of hairs that fell out during the pull test between the start (T 0) and end (T 180) of the study.

In the case of 17 of the 25 panelists (68%) the number of hairs lost during the pull test had dropped halfway through (T 90).

In the case of nine of the 25 panelists (36%), the number of hairs lost fell progressively as the study went on.

This means more hair was lost at the start of the study (T 0) than by halfway through it (T 90) and, in turn, more was lost at T 90 than by the end (T 180).



WASH TEST

The wash test results found that 19 panelists (76%) experienced a reduction in the number of hairs that fell out between the start (T 0) and end (T 180) of the study. A further four panelists (16%) saw a rise in the number of hairs falling out between the first and last wash tests. The remaining two (8%) had the same hair loss during the wash test at the start and end.

Of the 19 panelists who lost less hair by the end of the study, 14 were already showing a reduction in the number of hairs that fell out during the wash test halfway through (T 90). This means 56% of the panelists experienced a progressive reduction in hair loss during wash tests.

Adding the hairs that fell out during the pull test to those that fell out during the wash test confirms the efficacy of the study treatment. All panelists were losing substantially less hair by the end of the study than at the start or halfway through.

PANEL SURVEY

During each control visit to the C.T.C., panelists were asked about the features of the shampoo and lotion they were given to use, as well as the efficacy they perceived them as having.

Panelists considered the cosmetic qualities of the shampoo and lotion to be good. In general, the shampoo scored better than the lotion during all study phases. This was because the lotion caused dehydration or dryness of the scalp due to its alcohol content and the frequency of the application (daily).

With respect to the perceived efficacy of the treatment, panelists were satisfied with the results.

When asked about hair quantity, 16 of the 25 (64%) said they could see more hair by the end of the study (T 180). A further six (24%) said they could see the same amount of hair as at the start, i.e., they did not notice any further hair loss. This means that 88% of the panelists thought they had the same or more hair after using the treatment for six months.



This result was very high and confirms the regenerative efficacy of the study treatment. It should be said that these results were obtained from a single daily application of the treatment, compared to the two applications a day usually done in efficacy studies on anti hair-loss products.

As regards hair thickness, 13 panelists (52%) said their hair was thicker by the end of the study, compared to 11 (44%) who said it was the same. In other words, 96% of the panelists said their hair was just as thick or thicker after using the treatment for six months.

Hair thickness was not measured using any instrument to confirm the panelists' perceptions. However, the lotion did not contain any ingredient that artificially increases the feeling of hair thickness. The INCI formulation for the lotion did not list any ingredient that is a filmogen, or any hair thickening agents such as polymers or protein macromolecules that could confuse panelists with regard to the real thickness of their hair.

15 of the 25 panelists (60%) reported thinking their hair was growing more quickly by the end of the study, while nine said it was growing at the same speed as before (36%). The rise in hair-growth speed could be interpreted as a negative result in the case of androgenetic alopecia, as it could indicate a progression of the alopecia (together with shrinking of the follicle, hair loss and increased thinness of new hair). But in this case it does not seem to indicate that, because the trichogram examinations done in this study generally showed growth in size of the hair bulbs. Also, there was no hair loss, but rather regeneration (as the trichogram and pull- and wash-test results showed) and the growing hair was not perceived as being thinner. This means that the perception of increased hair-growth speed could be due to a rise in activity on the part of the matrix keratinocytes owing to stimulation caused by the study treatment.

The only adverse reactions the study treatment appeared to cause were desquamation (shedding of the skin) and itching among some panelists. Other changes could have been caused by the daily application of a product with a high alcohol content and seborregulator ingredients, which can cause moderate dehydration of the scalp and even lead to some loss of cells from the stratum corneum. Itching is also a result of scalp dehydration.

These symptoms cropped up among panelists with fine and/or dry skin that in principle requires a lower washing frequency than agreed upon for this efficacy study.



The adverse reactions that appeared could be minimised and might even disappear if hair were washed less often (e.g., up to twice a week) or if a less astringent shampoo were used.

The treatment also received positive comments from some of the panelists at the end of the study. One emphasised the reduction in seborrhoea of the scalp, and four said their hair looked better in general, with more body and vitality than at the start of the treatment.

In line with the above results, it comes as no surprise that the overall evaluation of the treatment was very positive. 22 of the 25 panelists (88%) said they were satisfied with the treatment at the end of the study (T 180).

88% of the panelists rated the treatment as “effective” or “very effective” at the end of the study (T 180).

With respect to the overall treatment, the average mark out of 10 they gave it at the end of the study was 7.4. Five panelists (20%) gave it a 9, equivalent to “excellent”.

The efficacy of the treatment would encourage the panelists to buy it. At the end of the study, 21 of the 25 panelists (84%) said they would buy the study treatment, even without knowing how much it cost. This once again confirms their satisfaction with the treatment results.



IV. CONCLUSIONS

From the results of Efficacy Study No. 07301 we can draw the following conclusions:

- The trichogram examination showed that 96% of the panelists experienced a rise in the proportion of hair in the anagen phase after using the study treatment for six months.
- A microscopic examination of the hair bulbs showed they had grown larger and had better-developed and more-hydrated outer sheaths by the end of the study.
- The images of the scalp obtained from filming with the micro-camera showed that, in general, there was a rise in hair density and thickness by the end of the study.
- All panelists lost less hair during the pull test after using the study treatment for six months.
- 76% of panelists had less hair loss in the wash test after using the study treatment for six months.
- The panelists considered the cosmetic qualities of the shampoo and lotion to be good.
- 64% of the panelists said they thought they had more hair by the end of the study.



- 88% of the panelists said they had the same or more hair by the end of the study; i.e., 88% maintained or increased the amount of hair after using the study treatment for six months.

- 52% of the panelists said their hair looked thicker by the end of the study.

- 96% of the panelists said their hair looked just as thick or thicker by the end of the study; i.e., 96% maintained or increased hair thickness after using the study treatment for six months.

- 60% of the panelists said their hair was growing faster by the end of the study.

- 88% of the panelists said they were satisfied with the treatment results at the end of the study.

- 88% of the panelists rated the treatment as “effective” or “very effective” at the end of the study.

- 84% of the panelists said they would buy the study treatment, even without knowing how much it cost.



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V. CERTIFICATION AND SIGNATURE

EFFICACY STUDY n^o.: 07301

START DATE: 20 november 2006

END DATE: 25 de may 2007

Report author:

I, MARÍA TERESA ALCALDE, hereby state that:

the present report accurately reflects the results obtained in the evaluation study.

María Teresa Alcalde

Pharmacist
Head of product evaluations, C.T.C.