

**EVALUATION OF THE
EFFECTIVENESS OF TREATMENT IN
REDUCING HAIR LOSS**

RUEBER S.L.



INFORME/REPORT

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EVALUATION OF THE EFFECTIVENESS OF TREATMENT IN REDUCING HAIR LOSS

RUEBER S.L.

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I. EVALUATION STUDY

1. TITLE

Evaluation of the effectiveness of hair treatment in reducing hair loss.

2. OBJECTIVES

2.1. PRIMARY OBJECTIVE

To investigate whether the application of a treatment tested produces a reduction in hair loss after 2 months of application.

2.2. SECONDARY OBJECTIVE

- ✓ To evaluate the effect of the treatment under study at different times through the self-perception of characteristics such as increased hair strength, increased vitality, reduced hair loss, increased number of new hairs, as well as issues related to the organoleptic characteristics and tolerance of the treatment.

3. EXPERIMENTAL DESIGN

3.1. TYPE OF STUDY

This study was single-center, with 1 intervention group that included 20 subjects with hair loss. The study was conducted according to the standard operating procedure of Centro de Tecnología Capilar, S.L. and in compliance with the regulations established in “Guía para investigaciones con seres humanos” (Guidelines for Research on Human Beings) and the guidelines of the Scientific Committee on Consumer Safety (SCCS).

4. LENGTH OF THE STUDY

60 days (2 months).

The next tests were carried out at the following times:

- ✓ T₀
 - Combing test
 - Wash test
 - Volunteer survey

- ✓ T₄₅
 - Combing test
 - Wash test
 - Volunteer survey

- ✓ T₆₀
 - Combing test
 - Wash test
 - Volunteer survey

5. ATTRIBUTES UNDER STUDY

The following attributes were evaluated in this study:

- ✓ Number of hairs extracted during the combing test.
- ✓ Number of hairs extracted during the wash test.
- ✓ Volunteer survey.

6. EQUIPMENT AND MATERIAL

The following items were required to conduct this study:

- ✓ Pean-Clamp.
- ✓ Disposable plastic capes.

7. VOLUNTEERS

Number of volunteers: 20.

Hair type: Varied.

Sex: 17 women and 3 men (85% women and 15% men)

Ages: 18 to 70 years (Average age 51 ± 11)

Table 1. Description of the volunteers according to sex and age

Volunteer	1	2	3	4	5	6	7	8	9
Sex	W	W	W	W	W	W	W	M	W
Age	52	64	46	48	44	56	53	43	67
Volunteer	10	11	12	13	14	15	16	17	18
Sex	W	W	W	W	W	W	W	M	W
Age	58	38	69	21	40	55	64	49	49
Volunteer	19	20							
Sex	W	M							
Age	51	61							

7.1. SELECTION CRITERIA

7.1.1. Inclusion criteria:

- Aged 18 to 70.
- Healthy volunteers with hair loss.
- No evidence of systemic diseases (e.g. heart or psychiatric disease etc.).
- Commitment not to use systemic topic or oral products with similar effects to that of the products to be tested throughout the study period.
- Do not change the daily routine.
- Commitment to keep the same hair length in the various visits to CTC.
- Having signed the written consent form and being informed of the study objective.
- Enough motivation and availability.

7.1.2. Non-inclusion / exclusion criteria:

- Do not sign the written consent.
- Allergy or hypersensitivity to any of the ingredients of the products tested.
- Scalp diseases: psoriasis, dermatitis, etc.
- Modification of the normal diet: hypocaloric diet, Atkins diet, etc.
- Pregnant volunteer.

7.2. CONSENT

Each volunteer was informed orally and in writing about the characteristics and objectives of the study. Each volunteer signed a written consent form and received a copy, with another copy kept on file at C.T.C.

7.3. INCIDENTS AND WITHDRAWALS

None.

8. FORMULAS

8.1. PRODUCTS UNDER STUDY

Product: **N1-Shampoo**

Ref. CD1724402

INCI: Aqua; Sodium Laureth Sulfate; Cocamidopropyl Betaine; Cocamide DEA; Quaternium-52; Sodium Chloride; PEG-75 Lanolin; PEG-6 Undecylenate; Parfum; Juniperus Oxycedrus; Styrene/Acrylates Copolymer; Lactic Acid; Sodium Benzoate; Methyl Chloro Isothiazolinone; Methyl Isothiazolinone; Magnesium Nitrate; Magnesium Chloride; C.I. 19140; C.I. 15985; C.I. 28440; C.I. 16255

Product: **N2-Tónico**

Ref. CD1724402

INCI: Alcohol Denat.; Aqua; Niacinamide; Urea; Undecylenic Acid; Tioxolone; Menthol; Imidazol; Lactic Acid; C.I. 19140; C.I.16035

Product: **N3 Tónico potenciado**

Ref. CD1724402

INCI: Aqua; Alcohol Denat; Parfum¹; PEG-40 Hydrogenated Castor Oil, Lactic Acid; Linalool; Eugenol; Cinnamal; D-Limonene; Benzyl Benzoate; L-Limonene; Cinnamyl Alcohol

¹ Cinnamomum Zeylanicum Oil; Eucalyptus Globulus Oil; Mentha Arvensis Oil; Thymus Vulgaris Oil.

Product: **N4-Capsule**

Ref. CD1724402

Composition: L-Cystine; L-Methionine; L-Cysteine; Wheat germ; Beer yeast; Iron gluconate; Zinc Gluconate; Heavy magnesium oxide; Vitamin E (DL-alpha tocopherol acetate 50%); Niacin (Nicotinamide, vit B3); L-Leucine; L-Threonine; L-Alanine; Pantothenic acid (Calcium D-Pantothenate, vit B5); Vitamin B6 (Pyridoxine HCl); Vitamin B2 (Riboflavin); Vitamin B1 (Thiamine HCl); Folate (Pteroylmonoglutamic acid, vit B9); Vegetable magnesium stearate (anti-caking agent); Microcrystalline cellulose (filler); Capsules 0 white jelly (wrap)

Manufactured by: Rueber S.L

9. PROTOCOL

9.1. BEFORE THE START OF THE STUDY (T₋₂)

The volunteers did not wash their hair 48 hours prior to the first visit to C.T.C., and they did not comb their hair 24 hours prior to this visit (T₀).

9.2. T₀

During the first visit to C.T.C., one specialist carried out the following:

- Combing test
- Wash test
- Volunteer survey

Each volunteer received:

- ✓ Enough product for 60 days of treatment and product application instructions
- ✓ An appointment for the next visit to C.T.C. (T₄₅)

9.3. IN THE VOLUNTEERS' HOMES

The volunteers applied the products according to the indicated guidelines:

Product: N1-Shampoo

- Use whenever you need to wash your hair.
- Apply in dry hair, leave on for 5 minutes.
- Rinse with water several times until no shampoo is left (add a bit of water and massage, doing this 3 or 4 times until there is no shampoo left) and do the second shampooing as normal.

Product: N2-Tónico

- Apply 3 pipet (women) and 2 pipet (men) of the product directly in the scalp opening partings and trying to wet the hair as little as possible. Later on, massage the scalp for 5 minutes. Not rinse off.
- Do the massage from the neck towards the top of the head to stimulate the blood flow. Open partings in your hair, pinching the scalp with the fingers of both hands to lift it away from the skull.
- Apply on alternate days, alternating with the Product N3: Tónico potenciado.

Product: N3 Tónico potenciado

- Apply 10 mL (women) and 5 mL (men) of the product in the scalp, opening partings and trying to wet the hair as little as possible. Later on, massage the scalp for 5 minutes. Not rinse off.
- Do the massaging from the neck towards the top of the head to stimulate the blood flow. Open partings in your hair, pinching the scalp with the fingers of both hands to lift it away from the skull.
- Apply on alternate days, alternating with the Product: N2-Tónico.

Product N4-Capsules

- Take 2 capsules with breakfast everyday.

9.4. T₄₅

The volunteers did not wash their hair 48 hours prior to the visit to C.T.C., and they did not comb their hair 24 hours prior to this visit (T₄₅)

In this visit to C.T.C., the following tests were carried out.

- Combing test

- Wash test
- Volunteer survey

Each volunteer received:

- ✓ An appointment for the next visit to C.T.C. (T_{60})

9.5. T_{60}

The volunteers did not wash their hair 48 hours prior to the visit to C.T.C., and they did not comb their hair 24 hours prior to this visit (T_{60}).

In this visit to C.T.C., the following tests were carried out.

- Combing test
- Wash test
- Volunteer survey

10. TESTS PERFORMED

10.1 COMBING TEST

The number of hairs falling out during hair combing under standardized conditions was determined.

After the regeneration treatment under study, the goal was for the number of hairs falling out during combing to be lower than the initial value.

10.1.1. Protocol

This was carried out at T_0 , T_{45} and T_{60} . As a precondition, the volunteers came to the visit without having washed their hair at least 48 hours before and without having combed their hair at least 24 hours before, in order to maintain the hairs which are near the end of telogen phase and avoid artificial reduction in the percentage of hairs in telogen phase.

The technician combed each volunteer's hair. The hair falling out – in the comb and on the cape – was collected for later counting.

10.2 . WASH TEST

The number of hairs falling out during hair washing under standardized conditions was determined.

After the regeneration treatment under study, the goal was for the number of hairs falling out during combing to be lower than the initial value.

10.2.1. Protocol

This was carried out at T_0 , T_{45} and T_{60} . As a precondition, the volunteers came to the visit without having washed their hair at least 48 hours before and without having combed their hair at least 24 hours before, in order to maintain the hairs which are near the end of telogen phase and avoid artificial reduction in the percentage of hairs in telogen phase.

The technician washed each of the volunteers' hair. The hair falling out was collected for later counting.

10.3 VOLUNTEER SURVEY

At T_0 , T_{45} and T_{60} the volunteers evaluated the general aspects of their hair.

II RESULTS

1. COMBING AND WASH TEST

VOLUNTEER	T ₀			T ₄₅			T ₀ vs.T ₄₅	T ₆₀			T ₀ vs.T ₆₀
	COMBING TEST T ₀	WASH TEST T ₀	COMBING + WASH TEST T ₀	COMBING TEST T ₄₅	WASH TEST T ₄₅	COMBING + WASH TEST T ₄₅	%REDUCTION IN HAIR LOSS T ₀ vs.T ₄₅	COMBING TEST T ₆₀	WASH TEST T ₆₀	COMBING + WASH TEST T ₆₀	%REDUCTION IN HAIR LOSS T ₀ vs.T ₆₀
1	99	125	224	41	56	97	-56,70	11	37	48	-78,57
2	133	364	497	50	309	359	-27,77	93	233	326	-34,41
3	216	634	850	101	227	328	-61,41	54	50	104	-87,76
4	113	220	333	43	42	85	-74,47	28	66	94	-71,77
5	140	334	474	79	155	234	-50,63	98	321	419	-11,60
6	139	134	273	150	143	293	7,33	60	133	193	-29,30
7	143	315	458	154	98	252	-44,98	62	91	153	-66,59
8	140	453	593	48	228	276	-53,46	81	364	445	-24,96
9	132	177	309	32	98	130	-57,93	28	79	107	-65,37
10	77	69	146	17	51	68	-53,42	25	59	84	-42,47
11	181	170	351	41	95	136	-61,25	19	29	48	-86,32
12	166	366	532	40	265	305	-42,67	21	205	226	-57,52



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13	138	51	189	367	131	498	163,49	205	483	688	264,02
14	153	421	574	45	283	328	-42,86	152	274	426	-25,78
15	98	95	193	21	49	70	-63,73	17	75	92	-52,33
16	185	151	336	14	38	52	-84,52	125	92	217	-35,42
17	31	90	121	7	72	79	-34,71	4	23	27	-77,69
18	97	129	226	73	449	522	130,97	56	365	421	86,28
19	77	295	372	19	219	238	-36,02	30	214	244	-34,41
20	68	318	386	8	106	114	-70,47	25	244	269	-30,31
Average							-38.57				-41.03

The values in red (highest and lowest value) are not taken into account in the calculation of the average value.

2. VOLUNTEER SURVEY

2.1. T₀

1. Currently, do you have hair loss (pillow, comb...)?

	Nº Responses	%
A lot	4	20,0
Quite	9	45,0
Neither much nor little	5	25,0
A little	2	10,0
Not at all	0	0,0

2. The hair that falls is:

	Nº Responses	%
Thick	3	15,0
Thin	12	60,0
Both	5	25,0

3. Do you notice your hair weaker?

	Nº Responses	%
A lot	4	20,0
Quite	9	45,0
Neither much nor little	3	15,0
A little	2	10,0
Not at all	2	10,0

4. Do you notice your hair thinner?

	Nº Responses	%
A lot	2	10,0
Quite	9	45,0
Neither much nor little	6	30,0
A little	3	15,0
Not at all	0	0,0

5. Do you notice a lack of volume?

	Nº Responses	%
A lot	3	15,0
Quite	4	20,0
Neither much nor little	6	30,0
A little	3	15,0
Not at all	4	20,0

6. Do you notice low hair density?

	Nº Responses	%
A lot	5	25,0
Quite	4	20,0
Neither much nor little	5	25,0
A little	3	15,0
Not at all	3	15,0

7. Do you have seborrhea/grease on the scalp?

	Nº Responses	%
A lot	2	10,0
Quite	1	5,0
Neither much nor little	6	30,0
A little	9	45,0
Not at all	2	10,0

8. Does your hair have shine?

	Nº Responses	%
A lot	1	5,0
Quite	3	15,0
Neither much nor little	9	45,0
A little	4	20,0
Not at all	3	15,0

9. Do you have dandruff?

	Nº Responses	%
A lot	0	0,0
Quite	2	10,0
Neither much nor little	1	5,0
A little	6	30,0
Not at all	11	55,0

10. Does your hair have frizz?

	Nº Responses	%
A lot	5	25,0
Quite	7	35,0
Neither much nor little	4	20,0
A little	2	10,0
Not at all	2	10,0

11. Does your hair get tangled?

	Nº Responses	%
A lot	2	10,0
Quite	7	35,0
Neither much nor little	5	25,0
A little	3	15,0
Not at all	3	15,0

12. Does you scalp itch?

	Nº Responses	%
A lot	0	0,0
Quite	2	10,0
Neither much nor little	5	25,0
A little	5	25,0
Not at all	8	40,0

13. Do you have a sensitive scalp?

	Nº Responses	%
A lot	1	5,0
Quite	4	20,0
Neither much nor little	5	25,0
A little	6	30,0
Not at all	4	20,0

14. Do you like your hair?

	Nº Responses	%
A lot	2	10,0
Quite	6	30,0
Neither much nor little	6	30,0
A little	4	20,0
Not at all	2	10,0

15. Other comments:

2.2. T₄₅

1. General opinion of:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	1	5,0	4	20,0	6	30,0	5	25,0
I like moderately	6	30,0	9	45,0	6	30,0	5	25,0
I like slightly	9	45,0	2	10,0	2	10,0	4	20,0
I neither like nor dislike	3	15,0	3	15,0	4	20,0	6	30,0
I dislike slightly	0	0,0	2	10,0	2	10,0	0	0,0
I dislike moderately	1	5,0	0	0,0	0	0,0	0	0,0
I dislike a lot	0	0,0	0	0,0	0	0,0	0	0,0

2. Appearance of:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	2	10,0	6	30,0	7	35,0	6	30,0
I like moderately	5	25,0	9	45,0	7	35,0	8	40,0
I like slightly	6	30,0	2	10,0	3	15,0	2	10,0
I neither like nor dislike	5	25,0	3	15,0	3	15,0	4	20,0
I dislike slightly	0	0,0	0	0,0	0	0,0	0	0,0
I dislike moderately	2	10,0	0	0,0	0	0,0	0	0,0
I dislike a lot	0	0,0	0	0,0	0	0,0	0	0,0

3. Fragrance:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	0	0,0	0	0,0	1	5,0	-	-
I like moderately	3	15,0	10	50,0	8	40,0	-	-
I like slightly	3	15,0	3	15,0	4	20,0	-	-
I neither like nor dislike	1	5,0	3	15,0	2	10,0	-	-
I dislike slightly	7	35,0	3	15,0	3	15,0	-	-
I dislike moderately	3	15,0	0	0,0	1	5,0	-	-
I dislike a lot	3	15,0	1	5,0	1	5,0	-	-

4. Color:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	0	0,0	7	35,0	5	25,0	6	30,0
I like moderately	6	30,0	10	50,0	9	45,0	8	40,0
I like slightly	3	15,0	1	5,0	3	15,0	3	15,0
I neither like nor dislike	5	25,0	2	10,0	2	10,0	3	15,0
I dislike slightly	3	15,0	0	0,0	1	5,0	0	0,0
I dislike moderately	3	15,0	0	0,0	0	0,0	0	0,0
I dislike a lot	0	0,0	0	0,0	0	0,0	0	0,0

5. Texture:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	4	20,0	7	35,0	8	40,0	-	-
I like moderately	11	55,0	10	50,0	7	35,0	-	-
I like slightly	1	5,0	1	5,0	2	10,0	-	-
I neither like nor dislike	3	15,0	2	10,0	3	15,0	-	-
I dislike slightly	0	0,0	0	0,0	0	0,0	-	-
I dislike moderately	1	5,0	0	0,0	0	0,0	-	-
I dislike a lot	0	0,0	0	0,0	0	0,0	-	-

6. Extensibility on the hair:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	3	15,0	8	40,0	8	40,0	-	-
I like moderately	11	55,0	7	35,0	8	40,0	-	-
I like slightly	3	15,0	3	15,0	2	10,0	-	-
I neither like nor dislike	3	15,0	2	10,0	2	10,0	-	-
I dislike slightly	0	0,0	0	0,0	0	0,0	-	-
I dislike moderately	0	0,0	0	0,0	0	0,0	-	-
I dislike a lot	0	0,0	0	0,0	0	0,0	-	-

7. Packaging comfort:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	7	35,0	8	40,0	7	35,0	8	40,0
I like moderately	5	25,0	4	20,0	4	20,0	7	35,0
I like slightly	3	15,0	3	15,0	3	15,0	2	10,0
I neither like nor dislike	3	15,0	4	20,0	5	25,0	3	15,0
I dislike slightly	0	0,0	0	0,0	0	0,0	0	0,0
I dislike moderately	1	5,0	0	0,0	0	0,0	0	0,0
I dislike a lot	1	5,0	1	5,0	1	5,0	0	0,0

8. Easy to use:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	9	45,0	8	40,0	8	40,0	7	35,0
I like moderately	5	25,0	5	25,0	4	20,0	8	40,0
I like slightly	2	10,0	3	15,0	4	20,0	2	10,0
I neither like nor dislike	2	10,0	2	10,0	2	10,0	1	5,0
I dislike slightly	1	5,0	1	5,0	1	5,0	2	10,0
I dislike moderately	0	0,0	0	0,0	0	0,0	0	0,0
I dislike a lot	1	5,0	1	5,0	1	5,0	0	0,0

9. Resistance and adaptation of the packaging:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	11	55,0	8	40,0	8	40,0	7	35,0
I like moderately	3	15,0	5	25,0	5	25,0	8	40,0
I like slightly	4	20,0	1	5,0	3	15,0	2	10,0
I neither like nor dislike	0	0,0	5	25,0	3	15,0	3	15,0
I dislike slightly	0	0,0	1	5,0	1	5,0	0	0,0
I dislike moderately	2	10,0	0	0,0	0	0,0	0	0,0
I dislike a lot	0	0,0	0	0,0	0	0,0	0	0,0

10. Product duration:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	8	40,0	8	40,0	8	40,0	8	40,0
I like moderately	8	40,0	5	25,0	6	30,0	9	45,0
I like slightly	4	20,0	3	15,0	1	5,0	1	5,0
I neither like nor dislike	0	0,0	4	20,0	4	20,0	2	10,0
I dislike slightly	0	0,0	0	0,0	1	5,0	0	0,0
I dislike moderately	0	0,0	0	0,0	0	0,0	0	0,0
I dislike a lot	0	0,0	0	0,0	0	0,0	0	0,0

11. Greasy sensation

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado	
	Nº Responses	%	Nº Responses	%	Nº Responses	%
Nothing	14	70,0	16	80,0	14	70,0
A little	6	30,0	4	20,0	6	30,0
Quite	0	0,0	0	0,0	0	0,0
A lot	0	0,0	0	0,0	0	0,0

12. Residue after applying the product:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado	
	Nº Responses	%	Nº Responses	%	Nº Responses	%
Nothing	19	95,0	17	85,0	17	85,0
A little	1	5,0	3	15,0	3	15,0
Quite	0	0,0	0	0,0	0	0,0
A lot	0	0,0	0	0,0	0	0,0

13. Using the product helps the hair grow

	Nº Responses	%
I totally agree	1	5,0
I agree	9	45,0
Neither agree nor disagree	10	50,0
I disagree	0	0,0
I totally disagree	0	0,0

14. After using the product, my hair has increased in volume and density

	Nº Responses	%
I totally agree	2	10,0
I agree	6	30,0
Neither agree nor disagree	10	50,0
I disagree	2	10,0
I totally disagree	0	0,0

15. The product favours hair thickening

	Nº Responses	%
I totally agree	2	10,0
I agree	4	20,0
Neither agree nor disagree	10	50,0
I disagree	4	20,0
I totally disagree	0	0,0

16. Use of the product can slow up the increase in hair loss

	Nº Responses	%
I totally agree	2	10,0
I agree	9	45,0
Neither agree nor disagree	9	45,0
I disagree	0	0,0
I totally disagree	0	0,0

17. Use of the product can slow up the increase in hair loss

	Nº Responses	%
I totally agree	3	15,0
I agree	7	35,0
Neither agree nor disagree	8	40,0
I disagree	2	10,0
I totally disagree	0	0,0

18. Hair loss on combing is considerably reduced when using the product

	Nº Responses	%
I totally agree	2	10,0
I agree	8	40,0
Neither agree nor disagree	10	50,0
I disagree	0	0,0
I totally disagree	0	0,0

19. The product meets the criteria required for an anti hair loss product

	Nº Responses	%
I totally agree	3	15,0
I agree	8	40,0
Neither agree nor disagree	9	45,0
I disagree	0	0,0
I totally disagree	0	0,0

20. The product can be used as a preventive treatment in persons liable to lose their hair early:

	Nº Responses	%
I totally agree	5	25,0
I agree	6	30,0
Neither agree nor disagree	9	45,0
I disagree	0	0,0
I totally disagree	0	0,0

21. Overall product rating

	Nº Responses	%
Very satisfying	1	5,0
Satisfying	10	50,0
Neither satisfactory nor unsatisfactory	9	45,0
Unsatisfactory	0	0,0
Very unsatisfactory	0	0,0

22. Overall product rating

	Nº Responses	%
Yes	12	60,0
No	8	40,0

23. Why?

Volunteers 2; 4; 5; 12; 13 and 17: I don't feel improvement

Volunteer 6: I don't like the shampoo

Volunteers 8; 10 and 19: I feel less hair loss

Volunteer 9: I feel more hair

Volunteers 11 and 15: I need more time for see the effects of the treatment

Volunteer 20: I feel more volume in my hair

24. If the product is suitable, intention to buy it rather than the usual one :

	Nº Responses	%
Surely yes	3	15,0
Probably yes	10	50,0
Surely no	5	25,0
Probably no	2	10,0

25. Side effects:

	Nº Responses	%
Yes	4	20,0
No	16	80,0

26. Describe:

Volunteers 3 and 6: Itch

Volunteers 10 and 13: I don't like the odor of the products

Volunteer 11: My hair is drier

Volunteer 17: I feel heat in the scalp

2.3. T₆₀

1. General opinion of:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	3	15,0	7	35,0	5	25,0	7	35,0
I like moderately	9	45,0	9	45,0	11	55,0	6	30,0
I like slightly	5	25,0	2	10,0	2	10,0	4	20,0
I neither like nor dislike	2	10,0	2	10,0	2	10,0	3	15,0
I dislike slightly	0	0,0	0	0,0	0	0,0	0	0,0
I dislike moderately	0	0,0	0	0,0	0	0,0	0	0,0
I dislike a lot	1	5,0	0	0,0	0	0,0	0	0,0

2. Appearance of:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	4	20,0	5	25,0	6	30,0	7	35,0
I like moderately	8	40,0	9	45,0	9	45,0	9	45,0
I like slightly	2	10,0	3	15,0	2	10,0	3	15,0
I neither like nor dislike	5	25,0	3	15,0	3	15,0	1	5,0
I dislike slightly	0	0,0	0	0,0	0	0,0	0	0,0
I dislike moderately	1	5,0	0	0,0	0	0,0	0	0,0
I dislike a lot	0	0,0	0	0,0	0	0,0	0	0,0

3. Fragrance:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	1	5,0	4	20,0	3	15,0	-	-
I like moderately	2	10,0	8	40,0	6	30,0	-	-
I like slightly	4	20,0	2	10,0	3	15,0	-	-
I neither like nor dislike	2	10,0	3	15,0	4	20,0	-	-
I dislike slightly	4	20,0	1	5,0	3	15,0	-	-
I dislike moderately	4	20,0	2	10,0	1	5,0	-	-
I dislike a lot	3	15,0	0	0,0	0	0,0	-	-

4. Color:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	2	10,0	6	30,0	7	35,0	7	35,0
I like moderately	7	35,0	7	35,0	8	40,0	9	45,0
I like slightly	2	10,0	5	25,0	3	15,0	3	15,0
I neither like nor dislike	4	20,0	2	10,0	2	10,0	1	5,0
I dislike slightly	3	15,0	0	0,0	0	0,0	0	0,0
I dislike moderately	2	10,0	0	0,0	0	0,0	0	0,0
I dislike a lot	0	0,0	0	0,0	0	0,0	0	0,0

5. Texture:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	4	20,0	7	35,0	7	35,0	-	-
I like moderately	8	40,0	9	45,0	9	45,0	-	-
I like slightly	5	25,0	2	10,0	2	10,0	-	-
I neither like nor dislike	2	10,0	2	10,0	2	10,0	-	-
I dislike slightly	0	0,0	0	0,0	0	0,0	-	-
I dislike moderately	1	5,0	0	0,0	0	0,0	-	-
I dislike a lot	0	0,0	0	0,0	0	0,0	-	-

6. Extensibility on the hair:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	7	35,0	10	50,0	7	35,0	-	-
I like moderately	9	45,0	7	35,0	9	45,0	-	-
I like slightly	1	5,0	2	10,0	3	15,0	-	-
I neither like nor dislike	2	10,0	1	5,0	1	5,0	-	-
I dislike slightly	1	5,0	0	0,0	0	0,0	-	-
I dislike moderately	0	0,0	0	0,0	0	0,0	-	-
I dislike a lot	0	0,0	0	0,0	0	0,0	-	-

7. Packaging comfort:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	9	45,0	6	30,0	5	25,0	8	40,0
I like moderately	3	15,0	7	35,0	9	45,0	10	50,0
I like slightly	4	20,0	3	15,0	2	10,0	2	10,0
I neither like nor dislike	2	10,0	3	15,0	3	15,0	0	0,0
I dislike slightly	0	0,0	1	5,0	1	5,0	0	0,0
I dislike moderately	0	0,0	0	0,0	0	0,0	0	0,0
I dislike a lot	2	10,0	0	0,0	0	0,0	0	0,0

8. Easy to use:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	11	55,0	7	35,0	7	35,0	8	40,0
I like moderately	3	15,0	7	35,0	7	35,0	9	45,0
I like slightly	3	15,0	2	10,0	3	15,0	0	0,0
I neither like nor dislike	1	5,0	2	10,0	1	5,0	3	15,0
I dislike slightly	0	0,0	2	10,0	2	10,0	0	0,0
I dislike moderately	0	0,0	0	0,0	0	0,0	0	0,0
I dislike a lot	2	10,0	0	0,0	0	0,0	0	0,0

9. Resistance and adaptation of the packaging:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	10	50,0	8	40,0	8	40,0	8	40,0
I like moderately	4	20,0	5	25,0	5	25,0	10	50,0
I like slightly	3	15,0	2	10,0	2	10,0	1	5,0
I neither like nor dislike	1	5,0	4	20,0	4	20,0	1	5,0
I dislike slightly	0	0,0	1	5,0	1	5,0	0	0,0
I dislike moderately	1	5,0	0	0,0	0	0,0	0	0,0
I dislike a lot	1	5,0	0	0,0	0	0,0	0	0,0

10. Product duration:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado		N4-Capsule	
	Nº Responses	%	Nº Responses	%	Nº Responses	%	Nº Responses	%
I like a lot	10	50,0	8	40,0	9	45,0	8	40,0
I like moderately	5	25,0	6	30,0	5	25,0	10	50,0
I like slightly	3	15,0	4	20,0	4	20,0	2	10,0
I neither like nor dislike	1	5,0	1	5,0	1	5,0	0	0,0
I dislike slightly	0	0,0	1	5,0	1	5,0	0	0,0
I dislike moderately	0	0,0	0	0,0	0	0,0	0	0,0
I dislike a lot	1	5,0	0	0,0	0	0,0	0	0,0

11. Greasy sensation:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado	
	Nº Responses	%	Nº Responses	%	Nº Responses	%
Nothing	16	80,0	16	80,0	17	85,0
A little	4	20,0	4	20,0	3	15,0
Quite	0	0,0	0	0,0	0	0,0
A lot	0	0,0	0	0,0	0	0,0

12. Residue after applying the product:

	N1-Shampoo		N2-Tónico		N3-Tónico Potenciado	
	Nº Responses	%	Nº Responses	%	Nº Responses	%
Nothing	20	100,0	19	95,0	18	90,0
A little	0	0,0	1	5,0	2	10,0
Quite	0	0,0	0	0,0	0	0,0
A lot	0	0,0	0	0,0	0	0,0

13. Using the product helps the hair grow

	Nº Responses	%
I totally agree	3	15,0
I agree	9	45,0
Neither agree nor disagree	8	40,0
I disagree	0	0,0
I totally disagree	0	0,0

14. After using the product, my hair has increased in volume and density:

	Nº Responses	%
I totally agree	4	20,0
I agree	10	50,0
Neither agree nor disagree	5	25,0
I disagree	1	5,0
I totally disagree	0	0,0

15. The product favours hair thickening

	Nº Responses	%
I totally agree	4	20,0
I agree	7	35,0
Neither agree nor disagree	5	25,0
I disagree	4	20,0
I totally disagree	0	0,0

16. The product favours hair thickening

	Nº Responses	%
I totally agree	5	25,0
I agree	10	50,0
Neither agree nor disagree	4	20,0
I disagree	1	5,0
I totally disagree	0	0,0

17. After using the product, my hair isn't so fragile and breakable

	Nº Responses	%
I totally agree	4	20,0
I agree	9	45,0
Neither agree nor disagree	5	25,0
I disagree	2	10,0
I totally disagree	0	0,0

18. Hair loss on combing is considerably reduced when using the product

	Nº Responses	%
I totally agree	7	35,0
I agree	9	45,0
Neither agree nor disagree	4	20,0
I disagree	0	0,0
I totally disagree	0	0,0

19. The product meets the criteria required for an anti hair loss product

	Nº Responses	%
I totally agree	7	35,0
I agree	8	40,0
Neither agree nor disagree	4	20,0
I disagree	1	5,0
I totally disagree	0	0,0

20. The product can be used as a preventive treatment in persons liable to lose their hair early

	Nº Responses	%
I totally agree	7	35,0
I agree	9	45,0
Neither agree nor disagree	3	15,0
I disagree	1	5,0
I totally disagree	0	0,0

21. Overall product rating

	Nº Responses	%
Very satisfying	4	20,0
Satisfying	12	60,0
Neither satisfactory nor unsatisfactory	1	5,0
Unsatisfactory	3	15,0
Very unsatisfactory	0	0,0

22. The product meets expectations

	Nº Responses	%
Yes	16	80,0
No	4	20,0

23. Why?

Volunteer 2: I think I need more time to evaluate the treatment.

Volunteer 4: I still notice hair fall and oily scalp.

Volunteer 6: It's complicate to use the whole treatment.

Volunteer 8, 10, 11, 12, 13, 14, 16 and 20: I notice less hair fall.

Volunteer 17: I feel my hair stronger.

Volunteer 15: I don't notice changes in my hair.

24. If the product is suitable, intention to buy it rather than the usual one :

	Nº Responses	%
Surely yes	5	25,0
Probably yes	12	60,0
Surely no	2	10,0
Probably no	1	5,0

25. Side effects:

	Nº Responses	%
Yes	2	10,0
No	18	90,0

26. Describe:

Volunteer 17: I feel my scalp hot after applying N2-Tónico

III. DISCUSSION

COMBING TEST AND WASH TEST

A way to determine the hair loss efficacy of the treatment under study is the determination of the number of volunteers where the treatment has had a positive effect over hair loss (decrease), neutral (no variation) or negative (increase). In figure 1 such percentage are represented.

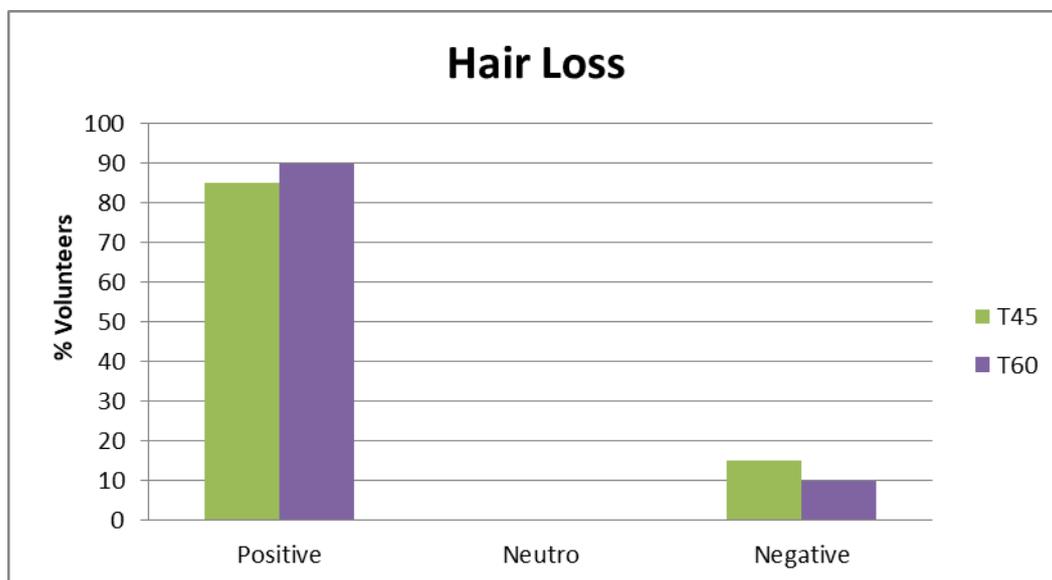


Figure 1: Effect of the treatment on hair loss.

It is considered positive (decrease), neutral (no change occurs) or negative (increase).

After 45 days of treatment we can observe that 85% of the volunteers have a reduction in hair loss. This reduction has an average value of 38.57% with a maximum value of 74.47%.

If we consider the total number of hairs (wash + combing) at the beginning of the experiment and after 45 days, and apply the t-test statistical criteria, we obtain that the differences are statistically significant ($p < 0.05$; CI: 95%).

At 60 days 90% of the volunteers have a decrease in hair loss, with an average value of 41.03% with a maximum value of 86.32%. Applying the t-test to the number of hairs lost at the beginning and at the end of the experiment, we obtain again that the difference are statistically significant ($p < 0.05$; CI: 95%).

VOLUNTEER ASSESSMENT SURVEY

In each of the control visits to C.T.C., at T_0 , T_{45} and T_{60} , the volunteers answered a survey with questions regarding the perceived efficacy of the treatment tested.

At T_0 they were asked about the perception that the volunteers had about their hair to take it as a starting point. At the remaining times, T_{45} and T_{60} , questions about the organoleptic characteristics of the treatment, the perceived efficacy, the global evaluation and the tolerance of the products were asked.

At the beginning of the study, the surveys sought to obtain an idea of the hair loss that the volunteers had, as well as the nature of it. These data are important to determine how the consumer's perception varies with the application of the treatment.

At the beginning of the experiment 100% of the volunteers have hair loss. This loss is related to 70.0% of the volunteers that notice low hair density.

As a result of this loss, 80.0% of the volunteers consider that their hair is weaker than normal and 65,0% indicate a lack of volume.

At the beginning of the experiment the perception for the properties of grease, shine and dandruff are the following:

Grease: 45.0% of the volunteers consider that their scalp is greasy.

Shine: 65.0% of the volunteers consider that their hair has shine.

Dandruff: 15.0% of the volunteers indicate the presence of dandruff on the scalp.

Regarding indicators of a damaged scalp such as sensitivity and itching, at the beginning of the experiment, 35.0% of volunteers have itching and 50.0% indicate that they have a sensitive scalp.

At the intermediate control point (T_{45}), in general there is a positive perception of the different products containing in the treatment. As for example, the general opinion of shampoo is positive in the 80.0% of the cases and in the case of capsules 70.0% of the volunteers have a positive opinion.

Appearance is also positively evaluated at least for the 65.0% of the volunteers in the different products included in the treatment.

On the other hand, color is also positively evaluated at least for the 45.0% of the volunteers in the different products included in the treatment.

For shampoo and different tonic, the extensibility on the hair is positively evaluated for the 85.0%, 90.0% and 90.0% of the volunteers respectively.

In general the easy to use is positively evaluated at least for the 80.0% of the volunteers in the different products included in the treatment.

At least 70.0% of volunteers don't feel oily scalp using the treatment, and 85.0% of them don't notice any residue after using the treatment.

With respect to the efficacy of the treatment, at 45 days from the beginning, 50.0% of the volunteers consider that the treatment helps hair' growth. In addition, 40.0% consider that their hair has more volume and density after 45 days of treatment.

As results of this, 55.0% of the volunteers consider that the treatment is useful to stop hair loss.

For the 55.0% of the volunteers, the treatment comply with the requirements for the anti-hair loss products and it can be useful as treatment to prevent hair loss for the 55.0% of volunteers.

After 45 days of treatment, 55.0% of the volunteers are satisfying or very satisfying with the treatment and for the 60.0% of the volunteers, the treatment fulfill their expectations.

On the other hand, the 65.0% of the volunteers would replace their usual product with the tested treatment.

Finally, 20.0% of the volunteers show some side effect after 45 days of treatment, mainly itching. However the intensity of itching as side effect was low, it was not directly related to the treatment application, and no volunteer quitted the study because side effects.

At the end of the study (T_{60}), volunteers kept the positive perception of the different products containing in the treatment. As for example, the general opinion of shampoo is positive in the

85.0% of the cases, 90.0% of volunteers have a positive opinion of both tonic tested and in the case of capsules 85.0% of the volunteers have a positive opinion.

Appearance is also positively evaluated at least for the 70.0% of the volunteers in the different products included in the treatment.

The fragrance of shampoo was positively evaluated only for the 35.0% of the volunteers.

On the other hand, color is also positively evaluated at least for the 55.0% of the volunteers in the different products included in the treatment.

For shampoo and tonics N2 and N3, the extensibility on the hair is positively evaluated for the 85.0%, 95.0% and 95.0% of the volunteers respectively.

In general the easy to use is positively evaluated at least for the 80.0% of the volunteers in the different products included in the treatment.

At least 80.0% of volunteers don't feel oily scalp using the treatment, and 90.0% of them don't notice any residue after using the treatment.

With respect to the efficacy of the treatment, at the end of the experiment, 60.0% of the volunteers consider that the use of this treatment helps hair' growth. In addition, 70.0% consider that their hair has more volume and density after 60 days of treatment.

As results of this, 75.0% of the volunteers consider that the treatment is useful to stop hair loss. Actually 80.0% notice less hair' loss after combing.

For the 75.0% of the volunteers, the treatment comply with the requirements for the anti-hair loss products and it can be useful as treatment to prevent hair loss for the 80.0% of volunteers.

After 60 days of treatment, 80.0% of the volunteers are satisfying or very satisfying with the treatment and fulfill their expectations.

On the other hand, the 85.0% of the volunteers would replace their usual product with the tested treatment.



INFORME/REPORT

Imp. 08.03-20
Edición 2

Finally, 10.0% of the volunteers show some side effect after 60 days of treatment, the intensity of them was very low.

IV. CONCLUSION

According to the results described in this study, the main conclusions obtained are:

❖ Hair loss

- At 45 days of treatment, 85% of the volunteers have a reduction in hair loss.
- This reduction has an average value of 38.57% with maximum values of up to 74.47%.
- The difference between the hairs lost at the beginning of the experiment and at T_{45} is statistically significant according to the t-test ($p < 0.05$; CI: 95%).
- At T_{60} , 90% of the volunteers have a decrease in hair loss.
- This reduction has an average value of 41.03% with maximum values of up to 86.32%.
- The difference between the hairs lost at the beginning of the experiment and at T_{60} according to the t-test criteria are statistically significant ($p < 0.05$; CI: 95%).

❖ Sensory evaluation

- T_0
 - ✓ 100% of the volunteers have hair loss and 70.0% of the volunteers notice low hair density.
 - ✓ 80.0% of the volunteers consider their hair to be weaker than normal and 65.0% indicate a lack of volume.
 - ✓ 45.0% of the volunteers consider that their scalp is greasy.
 - ✓ 65.0% of the volunteers consider that their hair has shine.
 - ✓ 15.0% of the volunteers indicate the presence of dandruff on the scalp.
 - ✓ At the beginning of the experiment, 35.0% of the volunteers have itching and 50.0% indicate that they have a sensitive scalp.
- T_{45}
 - ✓ There is a positive perception about the products that constitute the treatment.
 - ✓ At least, 70.0% of volunteers don't feel oily scalp using the treatment.
 - ✓ 85.0% of them don't notice any residue after using the treatment.
 - ✓ 50.0% of the volunteers consider that the treatment helps hair' growth.
 - ✓ 40.0% of volunteers consider that their hair has more volume and density.
 - ✓ 55.0% of the volunteers consider that the treatment is useful to stop hair loss and can be useful to prevent hair loss.
 - ✓ 55.0% of the volunteers are satisfying or very satisfying with the treatment.
 - ✓ 60.0% of the volunteers consider that the treatment fulfill their expectations.

- ✓ 65.0% of the volunteers would replace their usual product with the tested treatment.
- T₆₀
 - ✓ In general the organoleptic properties of the products are positively evaluated.
 - ✓ 80.0% of volunteers don't feel oily scalp using the treatment.
 - ✓ 90.0% of them don't notice any residue after using the treatment.
 - ✓ 60.0% of the volunteers consider that the treatment helps hair' growth.
 - ✓ 70.0% of volunteers consider that their hair has more volume and density.
 - ✓ 75.0% of the volunteers consider that the treatment is useful to stop hair loss.
 - ✓ 80.0% of volunteers notice less hair' loss after combing.
 - ✓ 80.0% of volunteers consider that this treatment can be useful to prevent hair loss.
 - ✓ 80.0% of the volunteers are satisfying or very satisfying with the treatment that fulfills their expectations.
 - ✓ 85.0% of the volunteers would replace their usual product with the tested ones.

V. CERTIFICATE AND SIGNATURE

Efficacy study no.: ID109-19

Done by: Centro de Tecnología Capilar, S.L.

Sponsor: RUEBER S.L.
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