Clinical study final report

Assessment of the anti-dandruff efficacy (using D-Squame® on 4 scalp areas) and of acceptability of a cosmetic product after a 28-day period of use under normal conditions of use

Investigational product	:	**ABIWASH SHAMPOO - REF : PICEA ABIES RESIN EXTRACT SHAMPOO**
IDEA Tests study number	:	**281682**
Investigator	:	**Caterina PAHOMI, Dermatologist**
Date of beginning of the study	:	**02/07/2021**
Date of end of the study	:	**30/07/2021**
Date of report	:	**24/08/2021**
Version	:	**1**

Sponsor
REPOLAR PHARMACEUTICALS OY
Suomalaistentie 7
02270 ESPOO
FINLAND

Place of study
CTI
Str. Iuliu Teodori, nr. 1
Sector 5
050496 BUCURESTI
ROMANIA

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AUTHENTICITY OF THE RESULTS

The study giving rise to this report was conducted under my responsibility, in accordance with the experimental protocol and in the spirit of Good Clinical Practice. I certify that this report precisely reflects the study conducted as well as the results obtained.

Caterina PAHOMI, investigator
Dermatologist

Signature / date:

Semnat digital de PAHOMI CATERINA
DN: cn=PAHOMI CATERINA, o=C.T.I, ou=C.T.I, email=cti.idea@gmail.com, c=RO
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The generated data were checked by CTI's Quality Assurance in accordance with the current procedures. This report was audited by IDEA Clinic's Quality Assurance. It accurately reflects the raw data of the study.

Signature / date:

Florence BERNARD
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IDEA TESTS GROUP
IDEA Clinic

1. PURPOSE OF THE STUDY

At the request of **REPOLAR PHARMACEUTICALS OY** company, we have assessed the anti-dandruff efficacy and the acceptability of the product:

ABIWASH SHAMPOO - REF : PICEA ABIES RESIN EXTRACT SHAMPOO
Code ID-21/04836

used under normal use conditions recommended by the sponsor, over a period of 28 days; and, generally speaking, we have assessed the ability of the product to keep the skin in good condition.

2. INVESTIGATIONAL PRODUCT

2.1. Characteristics

Name	:	ABIWASH SHAMPOO - REF : PICEA ABIES RESIN EXTRACT SHAMPOO
IDEA Tests code	:	ID-21/04836
Batch number	:	052022
Aspect	:	Liquid
Colour	:	Yellowish
Product type	:	Finished cosmetic product
Product class	:	Hair product
Storage conditions	:	Room temperature (20°C ± 5°C)
Expiry date	:	01/05/2022
Packaging	:	Plastic bottle
Number of received samples	:	25

2.2. Instructions for use during the study

Apply shampoo sparingly to wet hair 2-3 times a week, gently massage the shampoo to your hair and scalp, rinse off with plenty of water.

3. EXPECTED POPULATION BY PROTOCOL

3.1. Number of volunteers to be included

20 volunteers had to be included. Approximately 10% additional volunteers had to be recruited in order to obtain the appropriate number of volunteers at the end of the study.

3.2. Inclusion criteria

Volunteers meeting the following criteria had to be included:
- healthy volunteer;
- female or male gender;
- volunteer between 18 and 70 years old;
- all type of scalp and hair, with dandruff;
- without medical anti-dandruff treatment in the 3 months preceding the start of the study;
- no application of anti-dandruff cosmetic product 3 weeks before the beginning of the study;
- normal clinical examination prior to inclusion;
- non-allergic and non-atopic;
- not exhibiting any dermatological lesion on the examined site (scalp);
- no past history of allergy to cosmetics or household products;
- volunteer who has already used a product in the same category as that of the investigational product;
- volunteer who has signed a written free informed express consent;
- *if the volunteer was a woman:* woman who was not pregnant or not liable to become pregnant, woman who was not breastfeeding;
- volunteer able to understand the requirements of the study.

3.3. Non-inclusion criteria

Volunteers meeting the following criteria had to not be included:
- active scalp pathology, trichotillomania;
- volunteer with a general disease incompatible with the study;
- active dermatological disease;
- in receipt of anti-inflammatory drugs, corticosteroids, histamine antagonists, or any other treatment reducing or inhibiting inflammatory or allergic reactions; the prohibited medications are described in the current in-house manual;
- *if the volunteer was a woman:* woman who was pregnant, liable to become pregnant, or was breastfeeding;
- volunteer in the exclusion period between two studies;
- persistent dandruff.

3.4. Study imperatives

Throughout the study, each volunteer was asked:
- to attend all of the visits without having applied a hygiene, care and/or temporary colour product to the examined site;
- to do the last shampoo 3 days before each appointment at the study centre;
- not to intentionally or unintentionally expose theirself to UV light (natural or artificial);
- not to change their usual hygiene and cosmetic practices;
- not to use new cosmetic products;
- not to use another cosmetic product in the same class as that of the investigational product;
- to use the investigational product in place of their usual product;
- not to undergo aesthetic or dermatological procedure;
- not to undergo planned surgery;
- not to colour or bleach the hair;
- not to practise swimming;
- not to go to the hairdresser;
- *if the volunteer was a woman:* to continue using medically acceptable contraception to prevent pregnancy.

3.5 Specific study requirements and constraints relative to the Covid-19 epidemic

Taking into account the Covid-19 epidemic specific context, the volunteer was required to:
- inform the investigator of any contamination or the appearance of any symptom suggestive of Covid-19 during the study;
- inform the investigator of any contamination or the appearance of any symptom suggestive of Covid-19 concerning a person with whom he/she have been in contact during the study;
- follow the instructions given by the laboratory with regard to protective measures against Covid-19 detailed in the internal charter of the study Centre. These measures were communicated by phone, email and SMS; and displayed through billboard.

4. METHODOLOGY

The study was monocentric, open and comparative between D28 and D1 (cf. standard protocol 2.14 - version 1 of 26/03/2019).

4.1. Visit on D1

- Inform the volunteer about the study process;
- Collect signed, written, free, informed, express consent from the volunteer;
- Confirm that the inclusion and non-inclusion criteria are met;
- Allocate to the eligible volunteer an inclusion number in order of arrival into the study;
- Note in the case report form the treatments currently being taken by the volunteer;
- Identification of sampling areas: occipital and vertex (top of the skull) areas, right and left temporal areas;
- Application of D-squame® patches on the sampling areas by keeping the applicator (constant pressure) for 20 seconds;
- Removal of patches with tweezers;
- Application of D-squame® patches on an opaque black surface (for each patch, note the inclusion number, the area and the day of sampling);
- Give the investigational product and instructions for use;
- Remind the volunteer about the restrictions required by the study, in particular the need to do the last shampoo 3 days before the next appointment and to attend the visit without having applied product onto the examined sites;
- Arrange a new appointment on D28 with the volunteer.

4.2. Visit on D28

- Check that the protocol imperatives have been met;
- Check compliance of the applications;
- Recover the remaining product in its initial packaging;
- Note down the volunteer's impressions of the product's cosmetic qualities;
- Note in the case report form the treatments possibly being taken by the volunteer since the last visit;
- Identification of sampling areas: occipital and vertex (top of the skull) areas, right and left temporal areas;
- Application of D-squame® patches on the sampling areas by keeping the applicator (constant pressure) for 20 seconds;
- Removal of patches with tweezers;
- Application of D-squame® patches on an opaque black surface (for each patch, note the inclusion number, the area and the day of sampling);
- Record the possible clinical signs and/or symptoms of the volunteer.

5. RESULTS AND ANALYSIS

5.1. Experimental conditions

Study site : CTI, Str. Iuliu Teodori, nr. 1, Sector 5 - 050496 BUCURESTI - ROMANIA

Study dates
- Beginning : 02/07/2021
- End : 30/07/2021

5.1.1. Population analysed

Number of volunteers included : 23

Number of volunteers analysed : 23
- 21 women and 2 men
- average age of 58 years, between 47 and 70 years
- all type of scalp and hair, with dandruff

5.1.2. Protocol deviations

Inclusion number	Type of deviation	Deviation description	Degree of deviation impact	Decision taken	Comments
13	Individual consumption of the product	Did not bring back her packaging at the end of the study	Minor	-	Partial impact on the study results

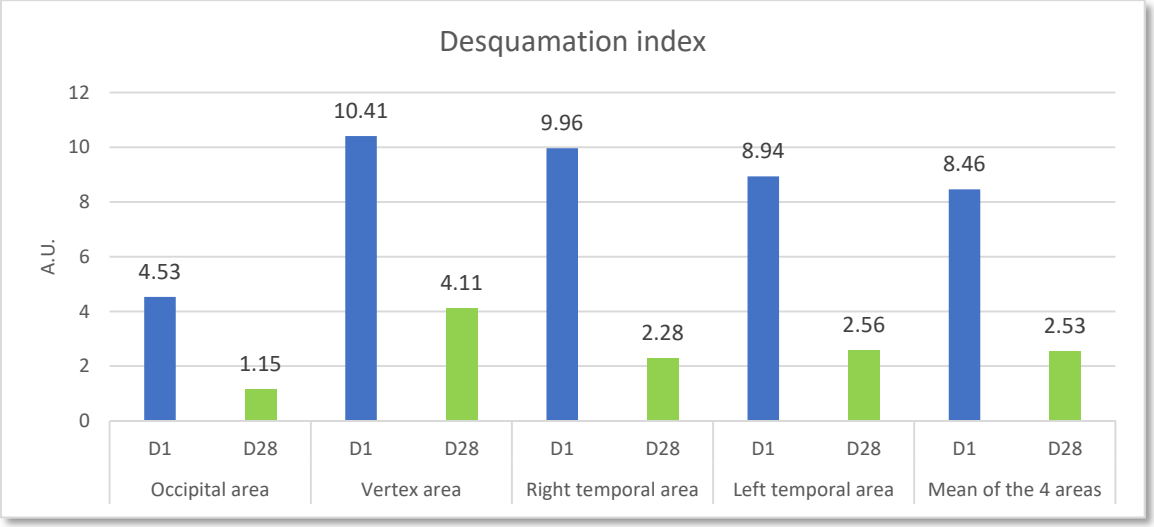
5.2. Results - discussion

5.2.1. Assessment of the anti-dandruff efficacy (n = 23)

- Desquamation index

	Desquamation index (A.U.)									
	Occipital area		Vertex area		Right temporal area		Left temporal area		Mean of the 4 areas	
	D1	D28	D1	D28	D1	D28	D1	D28	D1	D28
Mean	**4.53**	**1.15**	**10.41**	**4.11**	**9.96**	**2.28**	**8.94**	**2.56**	**8.46**	**2.53**
Standard deviation	5.20	1.55	10.81	5.65	8.00	2.08	8.56	3.71	7.04	2.92
Median	2.34	0.49	6.15	1.76	7.39	1.59	5.82	1.32	7.10	1.61
Minimum	0.28	0.16	0.58	0.26	1.56	0.20	0.36	0.25	1.94	0.26
Maximum	19.85	5.65	43.62	20.63	33.88	7.98	31.41	15.67	32.19	11.94
% of variation	**-74.5%**		**-60.5%**		**-77.1%**		**-71.3%**		**-70.1%**	
p value*	**< 0.000**		**0.001**		**< 0.000**		**< 0.000**		**< 0.000**	
Significance**	**S**		**S**		**S**		**S**		**S**	

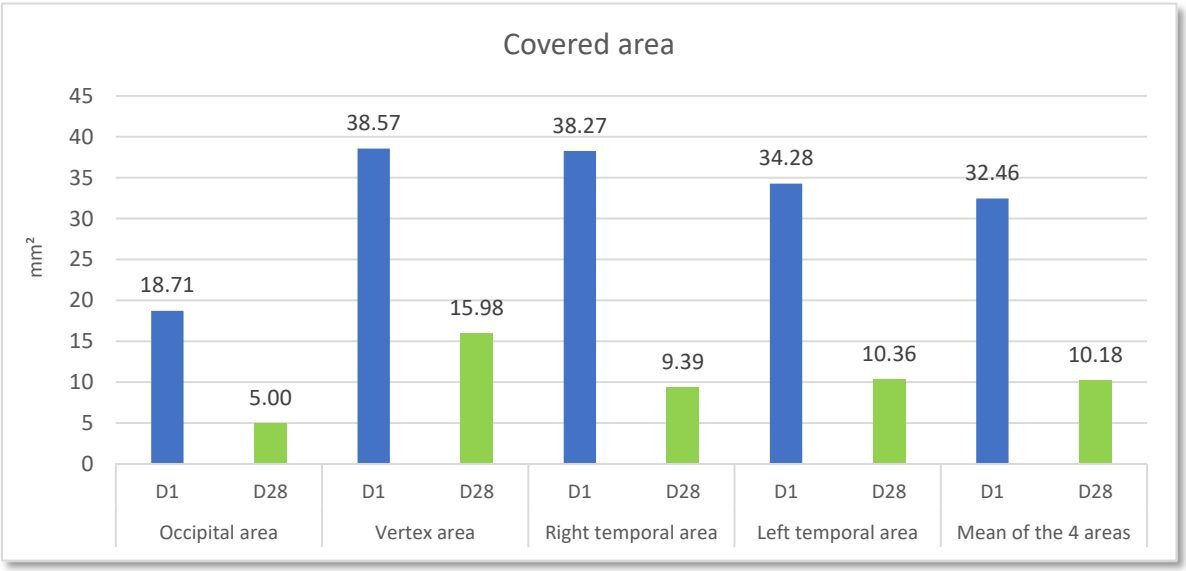
*Wilcoxon test for paired data - ** S: Significant (p ≤ 0,05) - NS: Non Significant (p > 0,05)



- Area covered by scales

	Covered area (mm²)									
	Occipital area		Vertex area		Right temporal area		Left temporal area		Mean of the 4 areas	
	D1	D28	D1	D28	D1	D28	D1	D28	D1	D28
Mean	**18.71**	**5.00**	**38.57**	**15.98**	**38.27**	**9.39**	**34.28**	**10.36**	**32.46**	**10.18**
Standard deviation	20.90	6.62	36.88	20.67	27.97	8.06	31.47	14.20	25.13	11.01
Median	10.41	2.22	26.35	7.83	29.23	7.03	25.92	5.67	27.47	6.73
Minimum	1.23	0.69	2.48	1.12	6.88	0.86	1.62	1.09	8.50	1.10
Maximum	80.65	24.57	145.60	71.95	119.16	30.03	117.52	58.91	115.73	46.02
% of variation	**-73.3%**		**-58.6%**		**-75.5%**		**-69.8%**		**-68.6%**	
p value*	**< 0.000**		**< 0.000**		**< 0.000**		**< 0.000**		**< 0.000**	
Significance**	**S**		**S**		**S**		**S**		**S**	

*Wilcoxon test for paired data - ** S: Significant (p ≤ 0,05) - NS: Non Significant (p > 0,05)



Analysis of samples taken using D-Squame® patchs exhibited a statistically significant decrease in the desquamation index and in the surface area covered by scales, on D28 compared to D1, on the 4 study areas, as well as on the average of the 4 areas.

5.2.2. Tolerance data

No clinical sign of intolerance was observed.
No sensation of discomfort was reported.

5.2.3. Cosmetic acceptability

The volunteers evaluated the properties of the product after a 28-day period of application:
- Overall satisfaction: 100%
- Purchasing intention: 21 volunteers out of 23
- Items related to efficacy of the product (positive responses ≥ 75% *):
    - The product does not weigh the hair down
    - The produt does not dry the hair out
    - The product gently cleanses the hair
    - The product does not cause any unpleasant skin reactions
    - The hair is shiny
    - The hair is light
    - The hair is supple
    - The hair is soft
    - The dandruff is less visible
    - The product washes the existing dandruff away
    - The product reduces dandruff
    - The product soothes the scalp
    - The product is suitable for your hair type

** Statistical significant threshold for 23 analysed volunteers*

6. CONCLUSION

Under the conditions of the study, the product:

ABIWASH SHAMPOO - REF : PICEA ABIES RESIN EXTRACT SHAMPOO
Code ID-21/04836

exhibited:
- **a statistically significant anti-dandruff efficacy;**
- **and an excellent cosmetic acceptability, with 100% favourable opinions.**

APPENDICES

- Characteristics of the volunteers
- Number of applications of the product
- Desquamation index (U.A.): individual data
- Area covered by scales (mm²): individual data
- Cosmetic acceptability of the product and volunteer comments
- Study report abstracts (in French and English)
- Standard protocol 2.14 - version 1 of 26/03/2019

Characteristics of the volunteers
ABIWASH SHAMPOO - REF : PICEA ABIES RESIN EXTRACT SHAMPOO

Inclusion no.	Initials	Sex	Age (years)	Type of scalp	Volunteer self-declaring sensitive scalp	Type of hair	Volunteer having dandruff	Current treatments
1	CA-GE	M	62	Oily	Yes	Oily	Yes	-
2	PR-GA	F	53	Normal	Yes	Normal	Yes	-
3	AN-LA	F	70	Oily	Yes	Oily	Yes	-
4	ST-NI	F	63	Dry	Yes	Dry	Yes	-
5	DI-LI	F	52	Oily	No	Oily	Yes	-
6	MI-IU	F	64	Oily	No	Dry	Yes	-
7	IG-RO	F	52	Oily	Yes	Oily	Yes	-
8	LA-IO	F	66	Oily	No	Normal	Yes	-
9	DU-MA	F	56	Normal	Yes	Dry	Yes	-
10	AN-TE	M	56	Normal	Yes	Normal	Yes	-
11	BA-DA	F	51	Dry	No	Dry	Yes	-
12	RA-TA	F	61	Oily	Yes	Oily	Yes	-
13	AI-RO	F	50	Oily	No	Normal	Yes	-
14	TI-AL	F	67	Dry	No	Dry	Yes	-
15	CR-CA	F	49	Oily	No	Oily	Yes	-
16	NA-CO	F	54	Oily	No	Normal	Yes	-
17	GE-IO	F	70	Dry	Yes	Dry	Yes	-
18	CI-MA	F	62	Oily	No	Normal	Yes	-
19	UR-FL	F	70	Normal	Yes	Dry	Yes	-
20	ST-EL	F	47	Oily	No	Oily	Yes	-
21	CA-MA	F	70	Dry	No	Dry	Yes	-
22	DI-MA	F	52	Oily	Yes	Oily	Yes	-
23	RU-AL	F	48	Oily	No	Normal	Yes	-

Number of applications
ABIWASH SHAMPOO - REF : PICEA ABIES RESIN EXTRACT SHAMPOO

Inclusion No.	Number of applications (scalp and hair)
1	8
2	12
3	9
4	9
5	12
6	9
7	9
8	8
9	10
10	10
11	9
12	10
13	9
14	9
15	10
16	9
17	9
18	9
19	10
20	12
21	8
22	11
23	8
Average	**10**

Desquamation index (U.A.): individual data
ABIWASH SHAMPOO - REF : PICEA ABIES RESIN EXTRACT SHAMPOO

Inclusion no.	Desquamation index (A.U.)									
	Occipital area		Vertex area		Right temporal area		Left temporal area		Mean of the 4 areas	
	D1	D28	J1	D28	J1	D28	J1	D28	J1	D28
1	1.23	0.80	2.84	2.23	1.79	1.59	3.38	1.39	2.31	1.50
2	0.68	0.66	3.41	1.76	5.17	3.96	4.97	2.39	3.56	2.19
3	0.76	1.08	16.53	2.65	2.91	0.51	1.75	0.52	5.49	1.19
4	2.34	0.56	1.08	0.79	5.36	0.51	0.36	0.42	2.29	0.57
5	2.26	1.50	6.13	1.08	10.72	1.13	5.62	3.02	6.18	1.68
6	0.53	0.16	0.58	0.42	1.56	0.20	5.82	0.25	2.12	0.26
7	11.92	1.72	12.88	6.15	7.39	4.03	10.63	4.05	10.70	3.99
8	6.54	1.21	8.12	4.95	17.67	3.27	12.04	1.56	11.09	2.75
9	0.89	0.24	2.27	1.24	3.79	0.27	0.81	0.39	1.94	0.53
10	2.68	5.65	2.11	1.28	4.46	0.88	1.04	1.85	2.57	2.41
11	7.37	0.26	23.49	10.82	5.59	4.91	8.16	3.89	11.15	4.97
12	0.81	0.23	25.01	9.80	1.84	0.92	1.14	0.44	7.20	2.85
13	3.99	1.85	6.15	3.13	16.58	3.79	3.24	1.32	7.49	2.52
14	0.39	0.26	1.79	0.29	2.07	0.44	20.73	0.39	6.25	0.35
15	0.70	0.27	6.08	2.38	7.33	3.68	14.28	7.38	7.10	3.43
16	19.85	0.17	43.62	0.85	33.88	1.91	31.41	0.49	32.19	0.86
17	4.62	0.31	7.61	0.29	13.57	1.58	8.03	0.49	8.46	0.67
18	4.10	0.40	2.39	0.71	9.97	0.38	1.19	0.38	4.41	0.47
19	0.28	0.18	1.17	0.26	8.01	2.19	2.23	0.37	2.92	0.75
20	1.54	0.33	8.10	2.64	13.37	1.92	10.07	1.54	8.27	1.61
21	14.78	2.67	16.59	20.63	16.37	5.96	26.24	9.65	18.50	9.73
22	5.73	0.49	26.53	1.65	18.39	0.52	15.30	1.06	16.49	0.93
23	10.19	5.57	15.00	18.51	21.38	7.98	17.10	15.67	15.92	11.94
Mean	**4.53**	**1.15**	**10.41**	**4.11**	**9.96**	**2.28**	**8.94**	**2.56**	**8.46**	**2.53**
Standard deviation	5.20	1.55	10.81	5.65	8.00	2.08	8.56	3.71	7.04	2.92
Median	2.34	0.49	6.15	1.76	7.39	1.59	5.82	1.32	7.10	1.61
Minimum	0.28	0.16	0.58	0.26	1.56	0.20	0.36	0.25	1.94	0.26
Maximum	19.85	5.65	43.62	20.63	33.88	7.98	31.41	15.67	32.19	11.94
% of variation	**-74.5%**		**-60.5%**		**-77.1%**		**-71.3%**		**-70.1%**	

Area covered by scales (mm²): individual data
ABIWASH SHAMPOO - REF : PICEA ABIES RESIN EXTRACT SHAMPOO

Inclusion no.	Covered area (mm²)									
	Occipital area		Vertex area		Right temporal area		Left temporal area		Mean of the 4 areas	
	D1	D28	J1	D28	J1	D28	J1	D28	J1	D28
1	5.23	3.31	11.68	8.89	7.85	6.67	14.14	5.95	9.72	6.20
2	3.00	2.95	14.84	7.83	21.98	16.88	21.29	10.66	15.28	9.58
3	3.31	4.79	57.94	11.59	12.97	2.21	7.77	2.32	20.50	5.23
4	10.41	2.47	4.76	3.52	23.59	2.29	1.62	1.88	10.10	2.54
5	9.94	6.58	26.15	4.22	42.48	4.85	24.40	11.60	25.74	6.81
6	2.35	0.69	2.48	1.78	6.88	0.86	25.92	1.09	9.41	1.10
7	41.53	7.62	44.87	22.74	29.23	15.35	34.78	16.27	37.60	15.50
8	27.62	5.34	31.91	20.95	60.93	14.19	45.91	6.73	41.59	11.80
9	4.00	1.04	10.18	5.15	16.24	1.19	3.60	1.71	8.50	2.27
10	11.96	24.57	9.26	5.58	19.84	3.83	4.64	8.06	11.43	10.51
11	30.84	1.15	76.95	41.91	21.18	18.91	28.67	17.06	39.41	19.76
12	3.57	1.03	95.44	40.52	8.09	3.97	5.04	1.92	28.04	11.86
13	15.66	8.15	23.49	11.77	58.05	15.40	12.66	5.67	27.47	10.25
14	1.75	1.15	8.00	1.29	9.23	1.94	83.07	1.71	25.52	1.52
15	3.06	1.16	26.35	10.54	29.01	16.31	53.21	32.05	27.91	15.02
16	80.65	0.73	145.60	3.78	119.16	8.58	117.52	2.15	115.73	3.81
17	20.10	1.29	33.26	1.26	57.01	7.03	34.19	2.13	36.14	2.93
18	18.16	1.79	10.47	3.08	42.88	1.67	5.31	1.61	19.20	2.04
19	1.23	0.79	5.22	1.12	34.45	9.02	9.89	1.60	12.70	3.13
20	6.81	1.46	32.31	10.88	52.71	8.48	34.89	6.08	31.68	6.73
21	61.33	11.43	64.11	70.27	56.49	23.91	87.37	36.47	67.33	35.52
22	24.41	2.22	98.61	6.98	69.87	2.30	65.15	4.66	64.51	4.04
23	43.44	23.20	53.18	71.95	80.03	30.03	67.37	58.91	61.01	46.02
Mean	**18.71**	**5.00**	**38.57**	**15.98**	**38.27**	**9.39**	**34.28**	**10.36**	**32.46**	**10.18**
Standard deviation	20.90	6.62	36.88	20.67	27.97	8.06	31.47	14.20	25.13	11.01
Median	10.41	2.22	26.35	7.83	29.23	7.03	25.92	5.67	27.47	6.73
Minimum	1.23	0.69	2.48	1.12	6.88	0.86	1.62	1.09	8.50	1.10
Maximum	80.65	24.57	145.60	71.95	119.16	30.03	117.52	58.91	115.73	46.02
% of variation	**-73.3%**		**-58.6%**		**-75.5%**		**-69.8%**		**-68.6%**	

Cosmetic acceptability of the product and volunteer comments
ABIWASH SHAMPOO - REF : PICEA ABIES RESIN EXTRACT SHAMPOO

Q1 Please note your inclusion number in double digits

Réponses obtenues : 23 Question(s) ignorée(s) : 0

#	RÉPONSES	DATE
1	23	8/3/2021 10:30 AM
2	22	8/3/2021 10:27 AM
3	21	8/3/2021 10:26 AM
4	20	8/3/2021 10:25 AM
5	19	8/3/2021 10:25 AM
6	18	8/3/2021 10:24 AM
7	17	8/3/2021 10:24 AM
8	16	8/3/2021 10:23 AM
9	15	8/3/2021 10:22 AM
10	14	8/3/2021 10:22 AM
11	13	8/3/2021 10:22 AM
12	12	8/3/2021 10:21 AM
13	11	8/3/2021 10:21 AM
14	10	8/3/2021 10:19 AM
15	09	8/3/2021 10:18 AM
16	08	8/3/2021 10:18 AM
17	07	8/3/2021 10:17 AM
18	06	8/3/2021 10:17 AM
19	05	8/3/2021 10:16 AM
20	04	8/3/2021 10:16 AM
21	03	8/3/2021 10:15 AM
22	02	8/3/2021 10:14 AM
23	01	8/3/2021 10:14 AM

Q2 Did you apply the product 2-3 times a week ?

Réponses obtenues : 23 Question(s) ignorée(s) : 0

CHOIX DE RÉPONSES	RÉPONSES	
YES	100.00%	23
If NO, why ?	0.00%	0
TOTAL		23

#	IF NO, WHY ?	DATE
	There are no responses.	

Q3 Did you apply the product the last day before the appointment of the end of the study ?

Réponses obtenues : 23 Question(s) ignorée(s) : 0

CHOIX DE RÉPONSES	RÉPONSES	
YES	100.00%	23
If NO, why ?	0.00%	0
TOTAL		23

#	IF NO, WHY ?	DATE
	There are no responses.	

Q4 ACCEPTABILITY

Réponses obtenues : 23 Question(s) ignorée(s) : 0

	COMPLETELY AGREE	AGREE	SLIGHTLY DISAGREE	DISAGREE	TOTAL	MOYENNE PONDÉRÉE
The odour is pleasant	30.43% 7	60.87% 14	4.35% 1	4.35% 1	23	91.30
The texture is pleasant	43.48% 10	56.52% 13	0.00% 0	0.00% 0	23	100.00
The packaging is practical	4.35% 1	91.30% 21	4.35% 1	0.00% 0	23	95.65
The product is pleasant to use	43.48% 10	56.52% 13	0.00% 0	0.00% 0	23	100.00
The product is easy to apply	52.17% 12	47.83% 11	0.00% 0	0.00% 0	23	100.00
The product is easy to rinse	34.78% 8	65.22% 15	0.00% 0	0.00% 0	23	100.00

Q5 EFFICACY

Réponses obtenues : 23 Question(s) ignorée(s) : 0

	COMPLETELY AGREE	AGREE	SLIGHTLY DISAGREE	DISAGREE	TOTAL	MOYENNE PONDÉRÉE
The product does not weigh the hair down	13.04% 3	82.61% 19	4.35% 1	0.00% 0	23	95.65
The produt does not dry the hair out	34.78% 8	65.22% 15	0.00% 0	0.00% 0	23	100.00
The product gently cleanses the hair	73.91% 17	21.74% 5	4.35% 1	0.00% 0	23	95.65
The product does not cause any unpleasant skin reactions	17.39% 4	82.61% 19	0.00% 0	0.00% 0	23	100.00
The hair is shiny	39.13% 9	56.52% 13	4.35% 1	0.00% 0	23	95.65
The hair is light	39.13% 9	56.52% 13	4.35% 1	0.00% 0	23	95.65
The hair is supple	69.57% 16	26.09% 6	4.35% 1	0.00% 0	23	95.65
The hair is soft	78.26% 18	17.39% 4	4.35% 1	0.00% 0	23	95.65
The dandruff is less visible	26.09% 6	73.91% 17	0.00% 0	0.00% 0	23	100.00
The product is effective from the first application	13.04% 3	60.87% 14	26.09% 6	0.00% 0	23	73.91
The product washes the existing dandruff away	30.43% 7	69.57% 16	0.00% 0	0.00% 0	23	100.00
The product reduces dandruff	30.43% 7	69.57% 16	0.00% 0	0.00% 0	23	100.00
The product soothes the scalp	39.13% 9	60.87% 14	0.00% 0	0.00% 0	23	100.00
The product is suitable for your hair type	34.78% 8	65.22% 15	0.00% 0	0.00% 0	23	100.00

Q6 OVERALL ASSESSMENT

Réponses obtenues : 23 Question(s) ignorée(s) : 0

	COMPLETELY AGREE	AGREE	SLIGHTLY DISAGREE	DISAGREE	TOTAL	MOYENNE PONDÉRÉE
Your impression of the product is good	43.48% 10	56.52% 13	0.00% 0	0.00% 0	23	100.00

Q7 What did you especially like about this product?

Réponses obtenues : 23 Question(s) ignorée(s) : 0

#	RÉPONSES	DATE
1	The texture, the odour	8/3/2021 10:30 AM
2	The hair is soft	8/3/2021 10:27 AM
3	The hair is soft	8/3/2021 10:26 AM
4	The product is easy to rinse, the texture	8/3/2021 10:25 AM
5	The product reduces dandruff, the product soothes the scalp	8/3/2021 10:25 AM
6	Everything	8/3/2021 10:24 AM
7	The hair is soft	8/3/2021 10:24 AM
8	The product soothes the scalp, the hair is soft	8/3/2021 10:23 AM
9	The hair is soft	8/3/2021 10:22 AM
10	Everything	8/3/2021 10:22 AM
11	The dandruff is less visible, the product soothes the scalp	8/3/2021 10:22 AM
12	The product gently cleanses the hair	8/3/2021 10:21 AM
13	The texture	8/3/2021 10:21 AM
14	The dandruff is less visible	8/3/2021 10:19 AM
15	The product soothes the scalp	8/3/2021 10:18 AM
16	The product reduces dandruff	8/3/2021 10:18 AM
17	The product gently cleanses the hair	8/3/2021 10:17 AM
18	The product gently cleanses the hair, the hair is supple	8/3/2021 10:17 AM
19	The hair is supple	8/3/2021 10:16 AM
20	The produt does not dry the hair out	8/3/2021 10:16 AM
21	The hair is soft	8/3/2021 10:15 AM
22	The product gently cleanses the hair	8/3/2021 10:14 AM
23	The product is pleasant to use, the odour	8/3/2021 10:14 AM

Q8 What did you especially dislike about this product?

Réponses obtenues : 23 Question(s) ignorée(s) : 0

#	RÉPONSES	DATE
1	The product weighs the hair down, the hair is not supple	8/3/2021 10:30 AM
2	Nothing	8/3/2021 10:27 AM
3	Nothing	8/3/2021 10:26 AM
4	Nothing	8/3/2021 10:25 AM
5	Nothing	8/3/2021 10:25 AM
6	Nothing	8/3/2021 10:24 AM
7	The product is not effective from the first application	8/3/2021 10:24 AM
8	The product is not effective from the first application	8/3/2021 10:23 AM
9	The odour	8/3/2021 10:22 AM
10	Nothing	8/3/2021 10:22 AM
11	Nothing	8/3/2021 10:22 AM
12	Nothing	8/3/2021 10:21 AM
13	The product is not effective from the first application	8/3/2021 10:21 AM
14	Nothing	8/3/2021 10:19 AM
15	The packaging	8/3/2021 10:18 AM
16	The product is not effective from the first application	8/3/2021 10:18 AM
17	The odour	8/3/2021 10:17 AM
18	The product is not effective from the first application	8/3/2021 10:17 AM
19	Nothing	8/3/2021 10:16 AM
20	Nothing	8/3/2021 10:16 AM
21	The product is not effective from the first application	8/3/2021 10:15 AM
22	Nothing	8/3/2021 10:14 AM
23	Nothing	8/3/2021 10:14 AM

Q9 Would you buy this product?

Réponses obtenues : 23 Question(s) ignorée(s) : 0

CHOIX DE RÉPONSES	RÉPONSES	
Yes	91.30%	21
No	8.70%	2
TOTAL		23

RESUME DU RAPPORT D'ETUDE

Promoteur	Moniteur	Lieu de réalisation
REPOLAR PHARMACEUTICALS OY Suomalaistentie 7 02270 ESPOO FINLAND	IDEA CLINIC Technopole Montesquieu 5, rue Jacques Monod CS 60077 33652 MARTILLAC CEDEX FRANCE	CTI Str. Iuliu Teodori nr. 1 Sector 5 050496 BUCURESTI ROMANIA

Investigateur : Caterina PAHOMI, Dermatologue
Références internes : 63427 - ID-21/04836

DESCRIPTION DE L'ETUDE

Evaluation de l'efficacité antipelliculaire (par D-squame® sur 4 zones du cuir chevelu) et de l'acceptabilité d'un produit cosmétique après utilisation sur une période de 28 jours dans les conditions normales d'emploi

Produit étudié : ABIWASH SHAMPOO - REF : PICEA ABIES RESIN EXTRACT SHAMPOO

Mode d'emploi retenu pour l'étude :
Appliquer une noisette de shampooing sur les cheveux 2 ou 3 fois par semaine, masser doucement le shampooing sur vos cheveux et votre cuir chevelu, rincer abondamment à l'eau.

Sites examinés : cuir chevelu et cheveux

Critères d'évaluation :
- évaluation de l'efficacité anti-pelliculaire : prélèvement de pellicules par patchs D-Squame® sur 4 zones du cuir chevelu : zones occipitale et vertex (sommet du crâne), zones temporales droite et gauche ; à J1 et J28 ; puis exploitation des prélèvements par analyse d'image avec calcul de l'indice de desquamation (U.A.), et de la surface occupée (mm²).
- données de tolérance : remontée des signes d'intolérance et/ou sensations d'inconfort par le volontaire à J28 ;
- acceptabilité cosmétique : questionnaire complété par le volontaire à J28.

RESULTATS - DISCUSSION

Dates de l'étude : du 02/07/2021 au 30/07/2021

Population analysée :
Nombre de volontaires inclus : 23
Nombre de volontaires analysés : 23
- 21 femmes et 2 hommes
- âge moyen de 58 ans, compris entre 47 et 70 ans
- tout type de cuir chevelu et de cheveux, avec des pellicules

Evaluation objective de l'efficacité antipelliculaire (n=23) :

	Indice de desquamation (U.A.)									
	Zone occipitale		Zone vertex		Zone temporale droite		Zone temporale gauche		Moyenne des 4 zones	
	J1	J28	J1	J28	J1	J28	J1	J28	J1	J28
Moyenne	**4,53**	**1,15**	**10,41**	**4,11**	**9,96**	**2,28**	**8,94**	**2,56**	**8,46**	**2,53**
Ecart type	5,20	1,55	10,81	5,65	8,00	2,08	8,56	3,71	7,04	2,92
Médiane	2,34	0,49	6,15	1,76	7,39	1,59	5,82	1,32	7,10	1,61
Minimum	0,28	0,16	0,58	0,26	1,56	0,20	0,36	0,25	1,94	0,26
Maximum	19,85	5,65	43,62	20,63	33,88	7,98	31,41	15,67	32,19	11,94
% de variation	**-74,5%**		**-60,5%**		**-77,1%**		**-71,3%**		**-70,1%**	
Valeur de p*	**< 0,000**		**0,001**		**< 0,000**		**< 0,000**		**< 0,000**	
Significativité**	**S**		**S**		**S**		**S**		**S**	

*Test de Wilcoxon pour données appariées - ** S : Significatif (p ≤ 0,05) - NS : Non Significatif (p > 0,05)

	Surface occupée (mm²)									
	Zone occipitale		Zone vertex		Zone temporale droite		Zone temporale gauche		Moyene des 4 zones	
	J1	J28	J1	J28	J1	J28	J1	J28	J1	J28
Moyenne	**18,71**	**5,00**	**38,57**	**15,98**	**38,27**	**9,39**	**34,28**	**10,36**	**32,46**	**10,18**
Ecart type	20,90	6,62	36,88	20,67	27,97	8,06	31,47	14,20	25,13	11,01
Médiane	10,41	2,22	26,35	7,83	29,23	7,03	25,92	5,67	27,47	6,73
Minimum	1,23	0,69	2,48	1,12	6,88	0,86	1,62	1,09	8,50	1,10
Maximum	80,65	24,57	145,60	71,95	119,16	30,03	117,52	58,91	115,73	46,02
% de variation	**-73,3%**		**-58,6%**		**-75,5%**		**-69,8%**		**-68,6%**	
Valeur de p*	**< 0,000**		**< 0,000**		**< 0,000**		**< 0,000**		**< 0,000**	
Significativité**	**S**		**S**		**S**		**S**		**S**	

*Test de Wilcoxon pour données appariées - ** S : Significatif (p ≤ 0,05) - NS : Non Significatif (p > 0,05)

L'analyse des prélèvements réalisés à l'aide des patchs D-Squame® a permis de mettre en évidence une diminution statistiquement significative de l'indice de desquamation et de la surface occupée par les squames à J28 par rapport à J1 sur les 4 zones d'étude, ainsi que sur la moyenne des 4 zones.

Données de tolérance :

- aucun signe clinique d'intolérance n'a été observé.
- aucune sensation d'inconfort n'a été rapportée.

CONCLUSION

Dans les conditions de l'étude, le produit a présenté :

- **une efficacité antipelliculaire statistiquement significative ;**
- **et une excellente acceptabilité cosmétique, avec 100 % d'opinions favorables.**

STUDY REPORT ABSTRACT

Sponsor	Monitor	Place of study
REPOLAR PHARMACEUTICALS OY Suomalaistentie 7 02270 ESPOO FINLAND	IDEA Clinic Technopole Montesquieu 5, rue Jacques Monod CS 60077 33652 MARTILLAC CEDEX FRANCE	CTI Str. Iuliu Teodori nr. 1 Sector 5 050496 BUCURESTI ROMANIA

Investigator : Caterina PAHOMI, Dermatologist
Internal references : 63427 - ID-21/04836

DESCRIPTION OF THE STUDY

Assessment of the anti-dandruff efficacy (using D-Squame® on 4 scalp areas) and of acceptability of a cosmetic product after a 28-day period of use under normal conditions of use

Investigational product: ABIWASH SHAMPOO - REF : PICEA ABIES RESIN EXTRACT SHAMPOO

Instructions for use during the study:
Apply shampoo sparingly to wet hair 2-3 times a week, gently massage the shampoo to your hair and scalp, rinse off with plenty of water.

Examined sites: scalp and hair

Assessment criteria:

- assessment of the anti-dandruff efficacy: dandruff sampling using D-Squame® patchs on 4 scalp areas: occipital and vertex (top of the skull) areas, right and left temporal areas, on D1 and D28; then exploitation of the samples by image analysis with calculation of the desquamation index (U.A.) and of the area covered by scales (mm²);
- tolerance data: report of possible signs of intolerance and/or feelings of discomfort by the volunteer on D28;
- cosmetic acceptability: questionnaire completed by the volunteer on D28.

RESULTS - DISCUSSION

Dates: from 02/07/2021 to 30/07/2021

Population analysed:
Number of volunteers included : 23
Number of volunteers analysed : 23
- 21 women and 2 men
- average age of 58 years, between 47 and 70 years
- all type of scalp and hair, with dandruff

Assessment of the anti-dandruff efficacy (n = 23):

	Desquamation index (A.U.)									
	Occipital area		Vertex area		Right temporal area		Left temporal area		Mean of the 4 areas	
	D1	D28	D1	D28	D1	D28	D1	D28	D1	D28
Mean	**4.53**	**1.15**	**10.41**	**4.11**	**9.96**	**2.28**	**8.94**	**2.56**	**8.46**	**2.53**
Standard deviation	5.20	1.55	10.81	5.65	8.00	2.08	8.56	3.71	7.04	2.92
Median	2.34	0.49	6.15	1.76	7.39	1.59	5.82	1.32	7.10	1.61
Minimum	0.28	0.16	0.58	0.26	1.56	0.20	0.36	0.25	1.94	0.26
Maximum	19.85	5.65	43.62	20.63	33.88	7.98	31.41	15.67	32.19	11.94
% of variation	**-74.5%**		**-60.5%**		**-77.1%**		**-71.3%**		**-70.1%**	
p value*	**< 0.000**		**0.001**		**< 0.000**		**< 0.000**		**< 0.000**	
Significance**	**S**		**S**		**S**		**S**		**S**	

*Wilcoxon test for paired data ** S: Significant (p ≤ 0.05) - NS: Non Significant (p > 0.05)

	Covered area (mm²)									
	Occipital area		Vertex area		Right temporal area		Left temporal area		Mean of the 4 areas	
	D1	D28	D1	D28	D1	D28	D1	D28	D1	D28
Mean	**18.71**	**5.00**	**38.57**	**15.98**	**38.27**	**9.39**	**34.28**	**10.36**	**32.46**	**10.18**
Standard deviation	20.90	6.62	36.88	20.67	27.97	8.06	31.47	14.20	25.13	11.01
Median	10.41	2.22	26.35	7.83	29.23	7.03	25.92	5.67	27.47	6.73
Minimum	1.23	0.69	2.48	1.12	6.88	0.86	1.62	1.09	8.50	1.10
Maximum	80.65	24.57	145.60	71.95	119.16	30.03	117.52	58.91	115.73	46.02
% of variation	**-73.3%**		**-58.6%**		**-75.5%**		**-69.8%**		**-68.6%**	
p value*	**< 0.000**		**< 0.000**		**< 0.000**		**< 0.000**		**< 0.000**	
Significance**	**S**		**S**		**S**		**S**		**S**	

*Wilcoxon test for paired data ** S: Significant (p ≤ 0.05) - NS: Non Significant (p > 0.05)

Analysis of samples taken using D-Squame® patchs exhibited a statistically significant decrease in the desquamation index and in the surface area covered by scales, on D28 compared to D1, on the 4 study areas, as well as on the average of the 4 areas.

Tolerance data:

- no clinical sign of intolerance was observed;
- no feeling of discomfort was reported.

CONCLUSION

Under the conditions of the study, the tested product exhibited:

- **a statistically significant anti-dandruff efficacy;**
- **and an excellent cosmetic acceptability, with 100% favourable opinions.**

Standard protocol 2.14

Assessment of the anti-dandruff efficacy (using D-Squame® on 4 scalp areas) and of acceptability of a cosmetic product after a X-day period of use under normal conditions of use

Protocol version	:	**1**
Author	:	**Christophe COURBIERE,** **Doctor of Pharmacy** **Scientific responsible of Efficacy and Solar studies**
Protocol date	:	**26 March 2019**

Monitor
IDEA Clinic
Montesquieu Site - CS 60077
5 rue Jacques Monod
33652 MARTILLAC
FRANCE

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GLOSSARY

The following terms and definitions apply for the purposes of this document:

Adverse effect: a harmful, undesired reaction occurring under normal conditions of use of the product in human beings or following misuse.

Adverse event: any harmful reaction occurring in a person taking part in the biomedical research whether or not this reaction is due to the research or to the product of which the research is being carried out.

Clinical sign: an adverse effect noted by the evaluator and/or the volunteer during the product use.

Exclusion from the study: exclusion of the volunteer on the decision of the investigator.

Exclusion: early discontinuation of the participation of a volunteer in the clinical study either by the person concerned or by the investigator.

Misuse: non-compliant use of the product with regard to its normal use, methods of use or specific precautions for use.

Protocol amendment: a change made deliberately to the protocol after the study start date.

Protocol deviation: a non-deliberate deviation from the protocol occurring after the study start date.

Serious adverse event: a reaction resulting in permanent or temporary functional incapacity, invalidity, hospitalisation; a reaction that is immediately life-threatening, or causes death or a congenital abnormality or malformation.

Symptom: an adverse effect experienced by the volunteer during use of the product (sensation of discomfort).

Volunteer: a healthy human being taking part voluntarily in a clinical study.

Withdrawal: a volunteer who is “lost to follow up” or withdraws his/her consent for a clinical study.

1. PURPOSE OF THE STUDY

To assess the anti-dandruff efficacy and acceptability of a cosmetic product used for a X-day period under normal conditions of use; and, generally speaking, to assess the ability of the product to keep the skin in good condition.

Depending on the sponsor's request, the study may be supplemented by:
- an assessment of efficacy of the product scored by the trained evaluator and/or volunteer;
- the taking of standardised photographs.

2. PRODUCT(S)

2.1. Investigational product

2.1.1. Characteristics

Name	:	*Information required to start the study*
IDEA Tests code	:	
Batch number	:	
Presentation	:	
Colour	:	
Type of product	:	
Class of product	:	
Storage conditions	:	
Expiry date	:	
Packaging	:	

2.1.2. Instructions for use during the study

The instructions for use will be provided by the sponsor. The IDEA Clinic technical team may change this on the basis of study claims and constraints with the agreement of the sponsor.

2.2. Reference product (comparative studies)

In the case of a comparative study, a reference product may be provided by IDEA Clinic or by the sponsor. The reference product used will be controlled on receipt, and registered, identified and labelled uniquely. The corresponding certificate of analysis will be stored and the information about the product will be re-copied into the study report.

2.3. Responsibility of the sponsor

The sponsor will communicate the data about the investigational product and guarantees that these are accurate. The sponsor will also supply the product(s) which is (are):
- formulated in compliance with Regulation (EC) No 1223/2009 of 30 November 2009 on cosmetics;
- manufactured according to Good Manufacturing Practice, guaranteeing physicochemical and microbiological quality which meets the manufacturer's specifications;
- formulated from ingredients with physicochemical and microbiological characteristics which comply with the manufacturer's specifications.

The data communicated must correspond in their entirety to the samples received.
The sponsor is the guarantor that the transport conditions for products sent to the IDEA Clinic are met.

2.4. Management

Each product received is controlled and identified with a unique code. Each product sample is (re)labelled in order to guarantee its traceability throughout the study.
The product samples will be stored at room temperature and may be exposed to light unless explicitly stipulated otherwise by the sponsor.
The remaining samples will be destroyed by a specialist company or may be returned to the sponsor at the sponsor's request.

3. STUDY POPULATION

3.1. General characteristics

3.1.1. Medical validation

Healthy subjects recruited from the IDEA Clinic general panel of volunteers or, where applicable, by its subcontractor. In order to be registered in the panel, each volunteer must undergo a medical validation by the recruiting centre doctor, provide evidence of social cover, and be an adult. From this panel, volunteers who meet the inclusion criteria are called up and then definitively included in the study at the end of the initial assessment.

3.1.2. Ethics and consent

Before being included, each volunteer is informed of:
- the purpose of the study;
- the constraints of the study and predictable risks, including those in the event of the study stopping prior to its term;
- the obligation to report any adverse event, any start of pregnancy, or any medication taken during the study;
- the length of the exclusion period, financial compensation sum, and the possibility to confirm the accuracy of data contained in the subject's clinical file and their subsequent archiving in sealed form;
- the possibility to stop the study at any time by informing the investigator.

This information is included in a written, free, informed, express consent form to participate in the study produced in duplicate and signed by the volunteer and the investigator. One copy will be stored by the volunteer and the other by the study centre.
If pictures are taken (depending on the sponsor's request), a contract of rights to the image will be signed by both parties.

3.1.3. Number of volunteers

A number of volunteers (men and/or women) defined in agreement with the sponsor will be included. Approximately 10% additional volunteers will be recruited in order to obtain the appropriate number of volunteers at the end of the study.

3.2. Inclusion criteria

Volunteers who meet the following criteria may be included:
- healthy volunteer;
- volunteer between 18 and 70 years old;
- all type of hair with dandruff;
- without medical anti-dandruff treatment in the 3 months preceding the start of the study;
- no application of anti-dandruff cosmetic product 3 weeks before the beginning of the study;
- normal clinical examination prior to inclusion;
- non-allergic and non-atopic;
- not exhibiting any dermatological lesion on the examined site (scalp);
- no past history of allergy to cosmetics or household products;
- volunteer who has already used a product in the same category as that of the investigational product;
- volunteer who has signed a written free informed express consent;
- woman who is not pregnant or not liable to become pregnant, woman who is not breastfeeding;
- volunteer able to understand the requirements of the study.

These criteria may be adjusted depending on the sponsor's request.

3.3. Non-inclusion criteria

Volunteers who meet the following criteria will not be included:
- active scalp pathology, trichotillomania;
- volunteer with a general disease incompatible with the study;
- active dermatological disease;
- in receipt of anti-inflammatory drugs, corticosteroids, histamine antagonists, or any other treatment reducing or inhibiting inflammatory or allergic reactions; the prohibited medications are described in the current in-house manual;
- woman who is pregnant, liable to become pregnant, or is breastfeeding;
- volunteer in the exclusion period between two studies;
- persistent dandruff.

3.4. Study imperatives

Unless otherwise specified by the sponsor, each volunteer will be asked to do the following throughout the study period:

- to attend all of the visits without having applied a hygiene, care and/or temporary colour product to the examined site(s);
- to do the last shampoo 3 days before each appointment at the study centre;
- not to intentionally or unintentionally expose him/herself to UV light (natural or artificial);
- not to change his/her usual hygiene and cosmetic practices;
- not to use new cosmetic products;
- not to use another cosmetic product in the same class as that of the investigational product;
- to use the investigational product in place of his/her usual product, if its category permits;
- not to undergo aesthetic or dermatological procedures;
- not to undergo planned surgery;
- not to colour or bleach the hair;
- not to practise swimming;
- not to go to the hairdresser;
- to continue using medically acceptable contraception to prevent pregnancy.

3.5. Exclusion criteria

This period varies depending on the study and the possible development of an adverse effect.

4. MATERIAL

All materials used in the study will be registered. These will be identified uniquely, consistently, and permanently in order to be listed and for the purposes of metrology monitoring.
Maintenance of materials is the responsibility of the IDEA Clinic senior member of staff. Monitoring of planning and the correct conduct of procedures are the responsibility of the senior metrology staff. Equipment maintenance is carried out depending on the type of equipment and following a planning schedule defined in-house, following the manufacturer's recommendations.

4.1. D-Squame® adhesive patches

Dandruff samples will be taken using D-squame® patches (CuDerm corp, Dallas, TX, USA). These transparent acetate discs of 22 mm in diameter have an adhesive side. They are equipped with a white rim without adhesiveness to facilitate their handling.
The patch is applied to the area of interest. After applying constant pressure for 20 seconds using a specific applicator, the patch is removed with tweezers and glued to an opaque black surface for later use by image analysis.

4.2. Equipment and software for image analysis of adhesive patches

The analysis of D-Squame® adhesive patches is performed using a Monaderm image analysis bench (Monaderm S.A.M., Monaco, MC) and dedicated Quantisquam® software. The patch to be analyzed is positioned in front of a homogeneous illumination. The presence of dandruff will induce phenomena of diffraction and reflection of the incident light, proportional to the quantity of dandruff taken; thus allowing quantification.

4.3. Device used for scoring *(depending on sponsor's request)*

Scoring will be made using an EVALUX BENCH table (Orion Concept SARL, Tours, France). This device is equipped with 3 daylight LED tubes (2 side tubes and 1 horizontal upper tube) allowing to score under stable and calibrated lighting. Thanks to a mirror, it also allows assessment under the same lighting and positioning conditions.

4.4. Picture taking device *(depending on sponsor's request)*

Depending on the intended purpose, standardised photographs may be taken using:
- either a BODY-HEASDCAN bench (Orion Concept) equipped with a NIKON D7000 camera;
- or a VISIOFACE system (Courage + Khazaka Electronic GmbH, Cologne, Germany);
- or a C-CUBE video-dermoscope (Pixience SAS, Toulouse, France).

5. METHODOLOGY

The study is single centre, open and comparative between DX and D1 and between Dinterm and D1 (depending on the sponsor's request).

5.1. Study process

5.1.1. Visit on D1

- Inform the volunteer about the study process;
- Collect signed, written, free, informed, express consent from the volunteer;
- Confirm that the inclusion and non-inclusion criteria are met;
- If the volunteer is eligible, allocate him/her an inclusion number in order of arrival into the study;
- Note in the case report form the treatments currently being taken by the volunteer;
- Identify sampling areas: occipital and vertex (top of the skull) areas, right and left temporal areas;
- Apply D-squame® patches on the sampling areas by keeping the applicator (constant pressure) for 20 seconds;
- Remove patches with tweezers;
- Apply D-squame® patches on an opaque black surface (for each patch, note the inclusion number, the area and the day of sampling);
- Carry out the scoring by the trained evaluator and/or the volunteer (depending on the sponsor's request);
- Take standardised photographs (depending on the sponsor's request);
- Give the investigational product previously weighed (if necessary) and instructions for use;
- Remind the volunteer about the restrictions required by the study, in particular the need to do the last shampoo 3 days before the next appointment and to attend the visits without having applied product onto the examined site(s);
- Arrange a new appointment on Dinterm or DX with the volunteer.

5.1.2. Visit on Dinterm (depending on sponsor's request)

- Check that the protocol imperatives have been met;
- Check compliance of the applications;
- Note down the volunteer's impressions of the product's cosmetic qualities (depending on the sponsor's request);
- Note in the case report form the treatments possibly being taken by the volunteer since the last visit;
- Identify sampling areas: occipital and vertex (top of the skull) areas, right and left temporal areas;
- Apply D-squame® patches on the sampling areas by keeping the applicator (constant pressure) for 20 seconds;
- Remove patches with tweezers;
- Apply D-squame® patches on an opaque black surface (for each patch, note the inclusion number, the area and the day of sampling);
- Record the clinical signs and/or symptoms of the volunteer if necessary;
- Carry out the scoring by the trained evaluator and/or the volunteer (depending on the sponsor's request);
- Take standardised photographs (depending on the sponsor's request);
- Remind the volunteer about the restrictions required by the study, in particular the need to do the last shampoo 3 days before the next appointment and to attend the visits without having applied product onto the examined site(s);
- Arrange a new appointment on DX with the volunteer.

5.1.3. Visit on DX

- Check that the protocol imperatives have been met;
- Check compliance of the applications;
- Recover the remaining product in its initial packaging to check the consumption (if necessary);
- Note down the volunteer's impressions of the product's cosmetic qualities;
- Note in the case report form the treatments possibly being taken by the volunteer since the last visit;
- Identify sampling areas: occipital and vertex (top of the skull) areas, right and left temporal areas;
- Apply D-squame® patches on the sampling areas by keeping the applicator (constant pressure) for 20 seconds;
- Remove patches with tweezers;
- Apply D-squame® patches on an opaque black surface (for each patch, note the inclusion number, the area and the day of sampling);
- Record the clinical signs and/or symptoms of the volunteer if necessary;
- Carry out the scoring by the trained evaluator and/or the volunteer (depending on the sponsor's request);
- Take standardised photographs (depending on the sponsor's request).

5.1.4. Data collection

The data will be re-copied as the study is conducted and will be recorded following the applicable procedures.

5.1.5. End of study rules

The study will end when all the included volunteers have presented to the end of study visit (except for exclusions).

5.2. Assessment criteria

5.2.1. Anti-dandruff efficacy

The dandruff sampling using D-Squame® patchs should be made by the same evaluator (investigator or clinical assistant under the responsibility of the investigator) throughout the study as far as possible.

Each D-Squame® patch will be analysed using the Quantisquam® software and the equipment described in § 4.2.

This analysis will allow to determine, for each volunteer, each time and each sampled area;
- the desquamation index (U.A.);
- the area occupied by scales (mm²).

5.2.2. Tolerance data

When the assessment of clinical and dermatological tolerance is not one of the defined objectives of the study, a collection of adverse events will nevertheless be made, and the adverse effects related to the products will be detailed in the study report without generating any analysis of the tolerance of the care protocol.

In the event of discomfort sensations (including any clinical signs observed) during the study, the evaluator will complete a specific document with the volunteer who will have, for example, the following criteria:
- tautness;
- redness;
- tingling sensation;
- dryness;
- small spots;
- itching;
- watering;
- swelling.

Each criterion will be scored from 0 to 3 (0 = absent, 0.5 = very mild, 1 = mild, 2 = moderate, 3 = severe).

5.2.3. Cosmetic acceptability

In order to assess the cosmetic acceptability, each volunteer will complete an individual questionnaire, about the cosmetic qualities of the investigational product.

5.2.4. Efficacy of the product by scoring *(depending on sponsor's request)*

In order to assess the efficacy of the product, the trained assessor and/or volunteer will rate each item defined by the sponsor using a specific scale.

5.3. Analysis of results

The volunteer's characteristics at inclusion and clinical data will be presented using descriptive statistics.

5.3.1. Assessment of anti-dandruff efficacy

For each parameter of the image analysis (desquamation index, area occupied by the scales), a summary table by measurement time will be constituted from the individual data. It will include the following descriptive statistics: mean, standard deviation, median, minimum, maximum as well as the percentages of variation at Dinterm compared to D1 (if applicable), at DX compared to D1, for each measured area, as well as for the average value of the 4 areas.

A statistical analysis will then be carried out for each parameter and each zone as well as for the average of the 4 zones, by comparing the values J1of DX with those of D1. This analysis will be performed using the Wilcoxon test for paired data, with a significance threshold set at $p \leq 0.05$, and the results will be reported in the summary table.

The effect of the tested product will be evaluated at DX and, if applicable, at Dinterm according to the direction and significance of the variations from D1.

5.3.2. Check consumption

In order to check the consumption of the product, each volunteer will be asked to do the following:
- to bring back his/her labelled sample (s) at the end of the study;
- to report in his/her acceptability questionnaire the compliance or non compliance with the instructions for use: number of applications, date and time of the last application.

Regarding some products or packaging (unidose for example), the consumption of the product will not be calculated if it does not provide relevant information.

5.3.2.1. Number of applications

The number of applications is calculated in accordance with the instructions for use of the study.
The number of applications will be considered as non-compliant if it is higher or lower than the number of specified applications with a margin of -/+ 10%.

Special case: if the instructions for use vary during the study ("at least three times a day", "once to twice a day", etc.), the number of applications will be considered as non-compliant if the value(s) do not meet the criteria. Such non-compliance will be noted in the study report; the consequences will be evaluated by the investigator who will take necessary actions, if appropriate.

5.3.2.2. Consumption

The average consumption of each volunteer is calculated as follows:

$$Average\ consumption = \frac{(initial\ quantity - final\ quantity}{number\ of\ applications\ *}$$

* number of applications by the volunteer

A standard deviation will be calculated based on all the consumptions of the panel of volunteers. The consumption of one volunteer will be considered as non-compliant if it is higher or lower than the average consumption, including the double standard deviation. Such non-compliance will be noted in the study report.

5.3.3. Assessment of cosmetic acceptability

In order to assess cosmetic acceptability, a specific questionnaire will be filled out by the volunteer. Unless otherwise defined in accordance with the sponsor, for each question, the volunteer will have to choose only one of the following answers: “completely agree”, “agree”, slightly disagree”, “disagree”. A “not concerned” answer can be added.

A percentage of satisfaction will be calculated for each question from positive opinions (“completely agree” and “agree”). Cosmetic qualities having a percentage of satisfaction at least equal to the Threshold Percentage of Statistical Significance* (TPSS) will be mentioned in the study report, and will be considered by the investigator as can be claimed by the sponsor.

The TPSS value depends on the total number of volunteers analysed. For the number of volunteers typically recruited, its value is indicated in the following table:

Panel	10 vols	15 vols	20 vols	30 vols	50 vols
Validity**	n=10-12	n=15	n=18-22	n=28-32	n=49-52
TPSS	90 %	80%	75%	70%	65%

* statistical test used: Z test for a proportion
** for n volunteers analysed

The investigator may draw a general conclusion as to cosmetic acceptability using the following scale:

Satisfaction percentage calculated based on the question “Your impression of the product is good”				
< 50 %	50 % - 59 %	60 % - 89 %	90 % - 99 %	100 %
Poor	**Average**	**Good**	**Very good***	**Excellent****

* From 15 volunteers analysed
** From 20 volunteers analysed

5.3.4. Assessment of efficacy of the product *(depending on sponsor's request)*

The assessment of efficacy using scores given by the trained assessor and/or volunteer will be performed, for each assessed item, by a statistical comparison of Dinterm scores (if applicable) and/or DX scores compared to D1 scores, using the Wilcoxon test for paired data with a significant threshold set at $\alpha = 0.05$. Results will be expressed as percentage variation.

5.4. Adverse events

5.4.1. Generalities

The following are distinguished:
- events unrelated to the product;
- adverse effects reported by the volunteer: sensations of discomfort (tingling, tight sensation, itching, etc.), including any clinical signs (redness, dryness, small spots);
- adverse effects noted by the assessor: clinical reactions seen (erythema, oedema, roughness, desquamation, papules, etc.)

5.4.2. Recording and management of adverse effects

Any adverse effect reported by the volunteer or noted by the assessor will be managed and recorded using the current in-house procedure.

5.4.3. Intensity

In order to assess the intensity of an adverse effect, the assessor will use the following descriptions:
- very mild: felt very weakly by the volunteer, but not requiring treatment and not interfering with the volunteer's everyday activities;
- mild: felt by the volunteer, but not requiring treatment and not interfering with the volunteer's everyday activities;
- moderate: discomfort, possibly requiring treatment, but not interfering with the volunteer's everyday activities;
- severe: very uncomfortable or even intolerable, requiring treatment and which may or may not interfere with the volunteer's everyday activities.

5.4.4. Attributability

The following must be determined whenever an adverse effect occurs:
- whether the time between exposure and occurrence of the symptoms is compatible;
- whether the symptoms are compatible with the cosmetic use.

The investigator will endeavour to establish the causal relationship between the occurrence of an adverse effect and the investigational product using the following descriptions:
- excluded/nil: a simultaneous disease, a simultaneous treatment or any other known cause are responsible for the adverse event, or the time course is incompatible;
- doubtful: this relationship exists if the adverse event follows a chronological sequence which is unlikely from the time of administration of the product and/or the type of reaction seen is poorly compatible with the category of product, with no history of reproduction or the same reaction occurring after a re-challenge with the product; re-challenge with the product is not deemed necessary by the investigator to draw a conclusion;
- possible: this relationship exists when the adverse event follows a reasonable chronological sequence from the time of administration of the product, when development is mostly occasional and when the type of reaction seen is compatible with the category of product although no re-challenge was deemed necessary by the investigator or the same reaction was not reproduced after re-challenge with the product;
- probable: this relationship exists when the adverse event follows a reasonable chronological course from the time of administration of the product and when the type of reaction found is compatible with the product category, when re-challenged with the product produced a reaction which was not clearly the same but was still suggestive or re-challenge was not deemed necessary by the investigator to draw a conclusion;
- very likely: this relationship exists when the adverse event follows a reasonable chronological sequence from the time of administration of the product and when the type of reaction observed is compatible with the product category with a history of confirmation of the reaction on re-challenge.

5.4.5. Pregnancies

Volunteers will not be included if they are suspected to be pregnant at inclusion.
If a volunteer is suspected to have become pregnant during the study, she will be excluded from the study. The cosmetic product will cease to be used as soon as the volunteer's pregnancy is known and the pregnancy will be monitored by the investigator until delivery.

5.5. Management in the event of exclusion

A volunteer may be excluded from the study for the following reasons:
- at his/her own request;
- on the decision of the investigator;
- following an adverse event;
- for administrative reasons.

In all cases, the sponsor will be informed of the exclusion and the reason for it. This will be clearly described in the study report. Volunteers excluded from the study will not be replaced.
If a volunteer is "lost to follow up", every efforts will be made to contact the volunteer and establish the corresponding reason.

5.6. Management in the event of protocol deviation

For each protocol deviation, the procedure to be followed is shown below:

Situation		Data included
Withdrawal		NO
Exclusion criterion during the study		NO
Failure to observe protocol	Major	NO
	Minor or acceptable	YES
Exclusion from the study due to the product		YES
Exclusion from the study not due to the product		NO
Volunteer incorrectly included		NO

All protocol deviations will be recorded in the report and the investigator will provide a decision as to its impact.
In emergency situations, the investigator will medically manage the volunteer following the appropriate procedure. The treatment and procedure will be notified to the sponsor as soon as possible.

5.7. Protocol amendment

Any change made to the protocol after the start of the study will be made in the form of an amendment.
Protocol amendments will be managed in the same way as the protocols.

6. LEGAL FRAMEWORK, ETHICAL AND LEGAL CONSIDERATIONS

6.1. Regulations

This study will be conducted in the spirit of the European directives on Good Clinical Practice. Without any therapeutic purpose, it will be conducted in accordance with the most recent recommendations of the World Medical Association (Declaration of Helsinki). It does not fall within the scope of French law on the protection of people taking part in research involving human person. No information will therefore be disclosed to the national file of people taking part in researches involving human person and the advice of the Committee for the protection of persons will not be sought.
The spirit of Decree on application of this law will however be respected.

6.2. Confidentiality

All details concerning the state of health of volunteers and the results of clinical examinations undertaken before the study (for volunteer recruitment selection and admission) are subject to medical confidentiality requirements pursuant to Article 378 of the French penal code and the medical deontology Code (Decree n° 95-1000 of 6 September 1995). These will, in no situation, be communicated to the sponsor with their identity. Data recorded before and during the study will be processed electronically. The study results related to the volunteer's participation may be revealed, but his/her identity will not be revealed/disclosed. In accordance with the General Data Protection Regluation (GDPR), volunteers can exercise their rights of access, rectification and limitation to the Data Protection Officer of IDEA Clinic. The IDEA Clinic Data Protection Policy is available at the following link: https://www.groupeideatests.com/volunteers/rgpd.html.

All study documents containing confidential information about the volunteers will be archived in the study dossier in a sealed envelope.
In order to maintain their anonymity, the volunteers taking part in the study will be identified by a 4-letter code containing the first two letters of their surname, followed by the first two letters of their forename. In addition, they will be allocated a number corresponding to their order of inclusion into the study.
The investigator and all people working in the study are bound by professional confidentiality with regard to the nature of the products studied, the study process, volunteers' data and the final results.

6.3. Insurance taken out by IDEA Clinic

The study will be covered by a liability insurance contract taken out by the sponsor covering studies on healthy volunteers.
The IDEA TESTS group has taken out an insurance contract guaranteeing the safety of volunteers.
Company name: COVEA RISKS.
Contract N°: 128 776 308
IDEA Clinic will ensure where appropriate that the subcontractor for the study has taken out appropriate insurance.

6.4. Quality management

6.4.1. Control of data

Each study dossier will be controlled by the IDEA Tests Group Quality Assurance Department or where applicable the Quality Assurance department of its subcontractors. This stage will confirm compliance of the study process with this protocol and with the in-house procedures for the IDEA Tests Group in the spirit of Good Clinical Practice. The final report will be audited by the IDEA Tests Group Quality Assurance department in order to guarantee that it accurately reflects the raw data generated and current procedures.

6.4.2. Qualification of staff

The investigator will ensure that staff taking part in the study possesses the competencies and accreditation approvals required to conduct the study.

6.5. ARCHIVING

The test facility will store documents concerning the study (final report, case report form, raw data) initially in its own archiving rooms. The study files will then be transferred to an approved archiving service company.

The study files will be stored for a period of 10 years for those studies on cosmetics. Beyond this time the data will be destroyed unless if specifically requested otherwise by the sponsor requesting that these be returned to it.

7. SIGNATURE

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IDEA Clinic