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Final Test Report

In an open (non-clinical) study 10 volunteers were provided with a hair gel which they applied to the scalp once daily. The product was used either overnight or allowed to remain on the scalp for at least 6 hours after application before any shampooing was done. A sufficient quantity of the hair gel packed in a dispenser was applied by pumping exactly 5 times and distributed on the scalp with gentle massage. The test product was based on an active ingredient derived from milk. In addition to the milk derived component the test product contained several vitamins of the B-group. Neither the supervising physician nor the volunteers were aware of the exact percentage of the composition.

The product was tested for its efficacy by studying a conventional hair follicle status (pluck trichogram) prior to and after at least 3 months' application of the hair gel. The conventional trichogram is the perfect method to study hair growth before and after or during therapy, provided evaluation is done in a standardized and accurate manner and defined preconditions have been observed. Among others, no intensive cosmetic hair treatments must have been used and no shampooing must have been done within 5 days prior to testing, because shampooing mechanically reduces the number of telogen hair and thus would falsify the result. This is important to note because decrease in telogen hair and increase in anagen hair are regarded as indicators of diminishing hair-loss. The method is recognized in dermatology and has been used to assess hair growth for decades.

In an open (non-clinical) pilot study 10 volunteers were using the mentioned hair gel in the manner described above, over a period of 3 months. 5 of the volunteers were women, 5 were men. The age range of the test panel was 23-65 years. The male test panel showed 3 cases of Alopecia androgenetica of the male pattern and 2 cases of the female pattern type. The female test panel showed 4 cases of Alopecia diffusa and 1 case of Alopecia androgenetica of the female pattern type.

Among the 5 men, a decrease in telogen (falling) hair was found in 4 cases and an increase in telogen hair in 1 case. Out of the 4 response cases, 2 showed a slight and 2 a distinct decrease in telogen hair.

In contrast, out of the 5 female volunteers 3 were found to show a distinct and 2 a slight decrease in the telogen rate. Simultaneously, 4 female volunteers showed a slight and 1 a distinct increase in anagen (growing) hair.

Summarizing the results of this pilot study, the hair gel was found to have tendency to diminish the number of telogen hair in the case of androgenetic Alopecia in men. The same could be observed in 1 female volunteer suffering from androgenetic Alopecia of the female pattern type. In contrast, a clear decrease in telogen hair was found in 3 of 4 female volunteers with Alopecia diffusa while using the hair gel. In 4 of 5 female volunteers, this decrease was found to coincide with a slight and in 1 case with a distinct increase in anagen hair.

The results of this pilot study allow to conclude that the hair gel used produces the best results in case of Alopecia diffusa in females. Nevertheless, diminished loss of hair was also observed in part of the male volunteers with androgenetic Alopecia.

A handwritten signature in black ink, appearing to read 'G. A. Lutz', with a stylized, cursive script.

(PD Dr. med. G. A. Lutz)

Test Results

**Pilot study conducted on human volunteers
with a gel formula containing 5% Follicusan**

1. Results obtained with individuals suffering from Alopecia diffusa

Patient: female						
Date of birth: 26.10.1963	Diagnosis: Alopecia diffusa (grade I)					
Patient No.: 9701						
	Anagen Hair %	Telogen Hair %	Catagen Hair %	Broken Hair %	Dystrophic Hair %	Total
Before treatment	66%	28%	6%			67
After 3 months of treatment	73%	25%			2%	44
Difference % before and after 3 months of treatment	+10.6%	-10.7%				

Patient: female						
Date of birth: 11.02.1939	Diagnosis: Alopecia diffusa (grade I)					
Patient No.: 6826						
	Anagen Hair %	Telogen Hair %	Catagen Hair %	Broken Hair %	Dystrophic Hair %	Total
Before treatment	72%	26%		2%		92
After 3 months of treatment	75%	16%		9%		118
Difference % before and after 3 months of treatment	+4.2%	-38.5%				

Patient: female						
Date of birth: 02.06.1935	Diagnosis: Alopecia diffusa (grade I)					
Patient No.: 1100						
	Anagen Hair %	Telogen Hair %	Catagen Hair %	Broken Hair %	Dystrophic Hair %	Total
Before treatment	63%	35%		2%		132
After 3 months of treatment	87%	11%	2%			44
Difference % before and after 3 months of treatment	+38.1	-68.6%				

Patient: female						
Date of birth: 12.07.1939	Diagnosis: Alopecia diffusa (grade I)					
Patient No.: 1240						
	Anagen Hair %	Telogen Hair %	Catagen Hair %	Broken Hair %	Dystrophic Hair %	Total
Before treatment	59%	14%		27%		74
After 3 months of treatment	62%	8%		25%	5%	83
Difference % before and after 3 months of treatment	+5.1%	-42.9%				

2. Results obtained with individuals suffering from Alopecia androgenetica

Patient: male						
Date of birth: 21.10.1977	Diagnosis: Alopecia androgenetica (female pattern type; grade II)					
Patient No.: 7255						
	Anagen Hair %	Telogen Hair %	Catagen Hair %	Broken Hair %	Dystrophic Hair %	Total
Before treatment	67%	32%		1%		113
After 3 months of treatment	67%	28%	1%	4%		91
Difference % before and after 3 months of treatment	0%	-12.5%				

Patient: female						
Date of birth: 07.10.1945	Diagnosis: Alopecia androgenetica (female pattern type; grade I)					
Patient No.: 4683						
	Anagen Hair %	Telogen Hair %	Catagen Hair %	Broken Hair %	Dystrophic Hair %	Total
Before treatment	69%	29%	2%			91
After 3 months of treatment	70%	25%		5%		154
Difference % before and after 3 months of treatment	+1.5%	-13.8%				

Patient: male						
Date of birth: 13.09.1952	Diagnosis: Alopecia androgenetica (male pattern type)					
Patient No.: 5751						
	Anagen Hair %	Telogen Hair %	Catagen Hair %	Broken Hair %	Dystrophic Hair %	Total
Before treatment	58%	38%	2%	2%		83
After 3 months of treatment	60%	35%	2%	2%		90
Difference % before and after 3 months of treatment	+3.5%	-7.9%				

Patient: male						
Date of birth: 23.09.1965	Diagnosis: Alopecia androgenetica (male pattern type)					
Patient No.: 9696						
	Anagen Hair %	Telogen Hair %	Catagen Hair %	Broken Hair %	Dystrophic Hair %	Total
Before treatment	50%	43%	1%	4%	2%	165
After 3 months of treatment	75%	14%		12%	2%	88
Difference % before and after 3 months of treatment	+50%	-67.4%				

Patient: male						
Date of birth: 31.08.1960	Diagnosis: Alopecia androgenetica (female pattern type)					
Patient No.: 4769						
	Anagen Hair %	Telogen Hair %	Catagen Hair %	Broken Hair %	Dystrophic Hair %	Total
Before treatment	77%	18%		3%	2%	57
After 3 months of treatment	88%	12%				43
Difference % before and after 3 months of treatment	+14.3%	-33.3%				

The test panel suffering from Alopecia androgenica included one non-response case:

Patient: male						
Date of birth: 22.10.1963	Diagnosis: Alopecia androgenetica (male pattern type)					
Patient No.: 9448						
	Anagen Hair %	Telogen Hair %	Catagen Hair %	Broken Hair %	Dystrophic Hair %	Total
Before treatment	72%	24%	1%	3%		71
After 3 months of treatment	59%	39%		1%	1%	89
Difference % before and after 3 months of treatment	-18.1%	+62.5%				

Attachment:

Formula of the tested gel containing 5% Follicusan

Formula used in Pilot Study

Gel with 5 % FOLLICUSAN

Phase	Component	%	Ref.
a)	Simulgel EG	2.50	(1)
	Water, distilled	69.50	
	Ethanol 96 % v/v	20.00	
	Polyglycol 400	3.00	(2)
b)	Follicusan	5.00	(*)

pH = 6.6

Manufacture

- a) mix thoroughly at room temperature;
- b) stir in.

References

- (1) Seppic
- (2) Hoechst
- (*) CLR
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