HAIR GROWTH

CLINICAL STUDY REPORT

Neofollics Hair Growth Stimulation Lotion

NEOFOLLICS
hair technology

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Abstract

Background

Neofollics Hair Technology has a long history of utilising the latest scientific breakthroughs in developing effective hair care products to combat hair problems. One of the key product lines of Neofollics is the Hair Growth Stimulating Line for thinning hair and hair loss. Part of this line is a targeted topical therapy. A well known topical therapy is the pharmaceutical product Minoxidil. Minoxidil is a well-known product, but side effects are very common and cannot be tolerated by many people for continued long term use. Neofollics Hair Technology has therefore developed an effective, user friendly, side effect free alternative to Minoxidil that enables people to use a topical treatment that fits into their daily routine.

Objectives

To assess the efficacy, tolerability and user satisfaction of the Neofollics Hair Growth Stimulating Lotion in men and women with thinning hair and hair loss.

Methods

The Neofollics Hair Growth Stimulating Lotion has been assessed in two studies: 1. An in-vitro study on the hair growth properties 2. An in-vivo study on 40 persons, both men and women within the age category 18-60 were treated with the Neofollics Hair Growth Stimulating Lotion, applied 2 times per day, 7 days per week for 90 days. Efficacy assessments included the decrease on hair loss, increase in hair growth and improvement of the hair quality.
Cosmetic performance indicators such as tolerabiltiy, user satisfaction and recommendation to others was also assessed.

Results

After 90 days of treatment both men and women perceived an increase on all assessment properties. A majority of persons see a reduction in hair loss and an improvement in hair growth. Only 8% of the users did not experience a visible effect. The user satisfaction is good in the majority of test persons and nobody seized the treatment due to adverse dermatological reactions and/or side effects.

Conclusion

The Neofollics Hair Growth Stimulating Lotion significantly promotes cell proliferation in human derma papilla cells and the comparison with Minoxidil confirms that the Neofollics Lotion has the potential to be more effective. In the in-vivo (real-life) study the majority of the users reported a positive outcome on the efficacy indicators for reduction in hair loss and growth of hair.

1. Introduction

Neofollics Lotion is developed to be an effective and user-friendly topical therapy to hair loss. The Lotion contains a balanced combination of proven active ingredients with multiple mechanisms addressing the complex biology of hair growth.

Studies on active ingredients and controlled observational investigations of the end formulation on men and women have verified the effectiveness of the Neofollics Lotion.

2. Working mechanisms

The Neofollics Lotion contains 3 hair growth molecules, 6 powerful plant extracts and 2 absorption enhancers. Each active ingredient has been selected based on scientific research to combat hair loss in multiple ways. The Lotion contains the hair growth molecules Adenosine, Vividine® and Aminexil®. The latter two molecules are analogues of Minoxidil, but do not have the known negative side effects common in Minoxidil.

The Neofollics Lotion works in 6 different ways to gain control over hair loss and improve the growth and appearance of the hair.

- Stimulate hair growth
- Prolong the hair growth phase
- Reduce inflammation, dandruff and itching
- Provides essential nutrients
- Increase health of scalp and hair follicles
- Increase resilience of the hair follicle against DHT (di-hydro-testosterone)

3. Overview of individual ingredients

Neofollics Lotion contains a 7% Neoxyl concentration which is a proprietary complex of hair growth molecules, peptides and botanical extracts:

1. Pyrrolidinyl diaminopyrimidine oxide (Vividine)
2. Diaminopyrimidine oxide (Aminexil)
3. Adenosine
4. Copper tri-peptide complex (GHK-Cu)
5. Ecklonia Cava Extract
6. Camellia sinensis leaf extract (EGCG)
7. Sanguisorba officinalis root extract
8. Raspberry Ketone
9. Carthamus Tinctorius extract

Neofollics Lotion also contains an Efficacy Booster™ which is a combination of ingredients to increase absorption of active ingredients and transport to the hair follicle:

1. Liposomes
2. Hyaluronic acid

ACTIVE INGREDIENT COMPLEXES

Neoxyl® is a powerful hair growth complex, developed by Neofollics Hair Technology. Neofollics Hair Technology helps people with hair problems by developing effective solutions. Numerous ingredients and formulations are researched with the aim to develop the most effective multilateral approach to hair loss.

With Neoxyl®, the ideal hair growth stimulating complex is now on the market. It contains a perfectly balanced combination of highly effective ingredients. The Neofollics Lotion contains a high concentration of Neoxyl®.

To obtain maximum results, the Neofollics Lotion includes Efficacy Booster™. A combination of Liposome technology and Hyaluronic Acid to rapidly and efficiently transport the active ingredients to where they can do their work: the hair follicle.

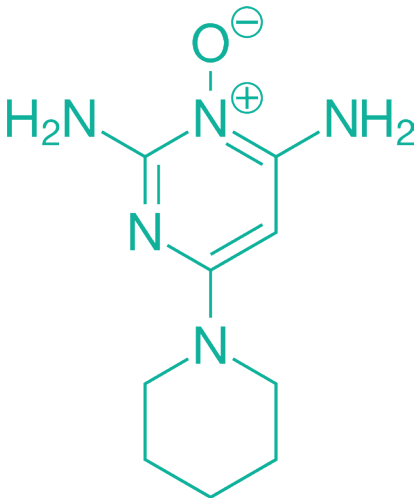
With this Lotion Neofollics created a new generation, highly effective anti-hair loss topical.

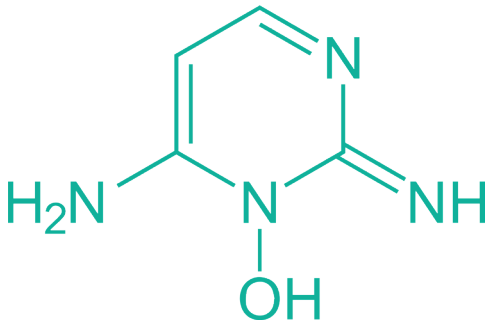
COMPARISON TABLE MINOXIDIL LOTION VS. NEOFOLLICS LOTION WITH NEOXYL®

Property	Minoxidil	Neoxyl®
Concentration of active ingredients	2% (women), 5% (men)	7% (for both men and women)
Side effects	Yes, common are: - Lower blood pressure - Dizzyness	Not indicated
Composed of number of active ingredients	1	10+
DHT combatting	No	Yes, in several ways: - Reducing scalp DHT concentration* - Increasing resilience of hair follicles against DHT* * Based on scientific studies performed on the ingredients in Neoxyl®
Hair growth stimulating & supporting	Yes, - Ion channel opening* * Based on scientific studies	Yes, in several ways - Ion channel opening* - Anti inflammation, - Anti fibrosis* - Improvement of scalp condition - Provision of nutrients * Based on scientific studies performed on the ingredients in Neoxyl®
Impact on hair and scalp condition	Can cause irriration, redness and itching due to high Propylene Glycol (PPG) concentration	Soothes and improves the scalp and hair condition
Success rate	Between 60-80% (various studies)	92%
User satisfaction rate	~30% (various studies)	95%

4. Key ingredients and their functions

The active ingredients in the Neofollics Hair Growth Stimulating Lotion are described on the following pages. The lotion is composed of botanical extracts and individual molecules with specific working mechanisms on hair growth.





1. VIVIDINE

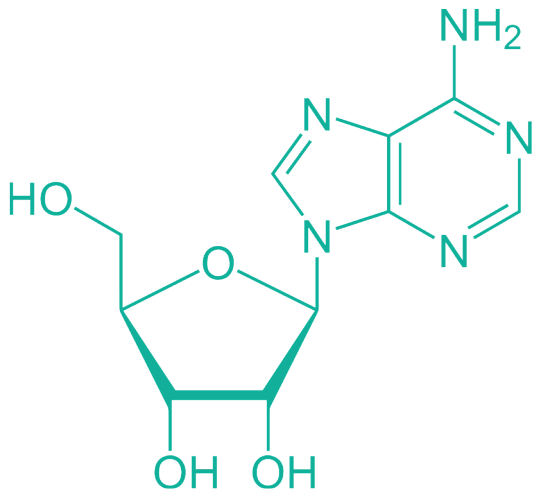
Stimulates hair growth in multiple ways. Vividine allows for potassium channel opening (PCO), just like Minoxidil. This causes the hair to enter the growth phase quicker and for the growth phase to last longer. Vividine also stimulates the blood supply to the hair follicles, allowing nutrients to reach the follicles more easily.

Clinical study results as single ingredient indicate a 13,5% increase on the improvement of mRNA expression for Vividine as compared with Minoxidil 5% which gives a 6,4% increase.

2. AMINEXIL

The main function of Aminexil is to prevent hardening of collagen around the hair root, making the hair roots anchor themselves more firmly into the scalp, thus reducing hair loss.

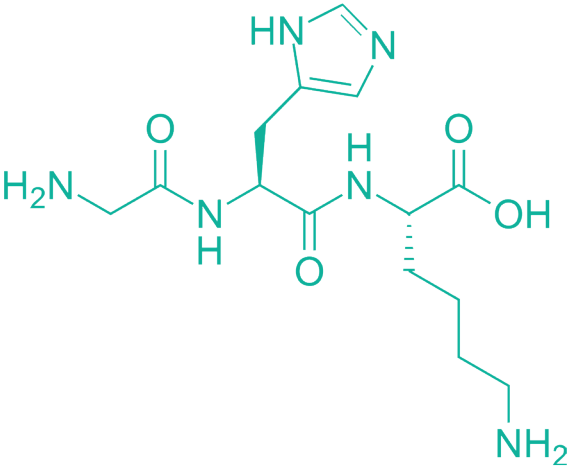
A clinical study result on the single ingredient indicated an improvement on hair loss at 58% of man and 47% of women after 12 weeks. The telogen rate of hairs decreased with 7,7% and the anagen count improved by 8,1%



3. ADENOSINE

Studies show that applying a solution of Adenosine on the scalp can allow for improved hair growth in both men and women. Compared to Minoxidil, users are more satisfied using Adenosine in the prevention of hair loss. And unlike Minoxidil, Adenosine does not have any significant side effects.

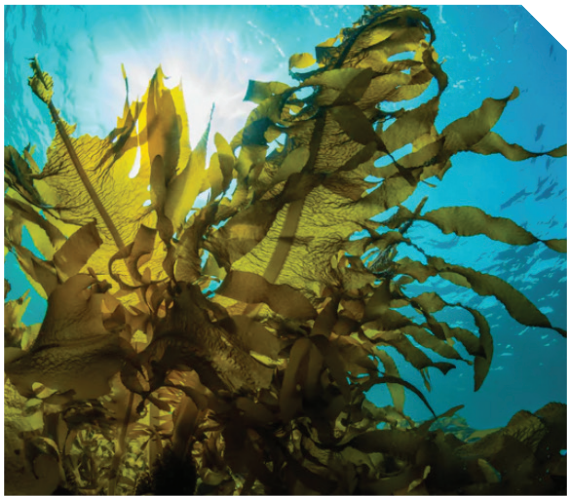
Studies on Adenosine indicate a significant increase of hair growth among terminal hairs and an overall improvement of the hair status among both men and women



4. COPPER PEPTIDE COMPLEX

Copper tripeptide-1, also known as GHK-Cu is a protein composed of three amino acids, glycine, histidine and lysine. GHK-Cu is widely known for hair growth and anti-inflammatory properties.

Multiple studies indicate a hair growth effect comparable to Minoxidil 5%. Furthermore GHK-Cu increased the number of anagen hair follicles by 80% after 3 months of treatment.



5. ECKLONIA CAVA

Is a seaweed from the waters of South Korea. Ecklonia cava is a natural alternative to Finasteride and Minoxidil. It contains a high concentration of the substance Dieckol, which has a DHT lowering effect and a high concentration of Dioxinodehydroeckol, which stimulates hair growth.

6. EGCG (EPIGALLOCATECHIN GALLATE)

A polyphenol from Green Tea. EGCG inhibits the process of 5a-reductase. This makes it a natural DHT inhibitor that stimulates hair growth.

7. SANGUISORBA OFFICINALIS

A plant that belongs to the rose family. Sanguisorba officinalis stimulates hair growth by prolonging the growth phase of the hair follicles.

It suppresses Fibroblast Growth Factor-5 (FGF-5), a natural protein that plays a role in the (too rapid) transition of the hair from the telogen to the anagen phase.

8. RASPBERRY KETONE

An extract from raspberry. Raspberry ketone increases the production of IGF-1 (an insulin-like growth factor), which stimulates the growth of the hair follicle. Studies show that a very low concentration of this substance already has a significant effect on hair growth.

9. CARTHAMUS TINCTORIUS

A thistle-like plant. Carthamus tinctorius stimulates hair growth in different ways and suppresses growth factor B-1, a peptide which is associated with hair loss.

EFFICACY BOOSTER™

The Neofollics Lotion contains Efficacy Booster™ to improve the penetration of the active ingredients in to the scalp.

Hyaluronic acid improves the condition of the skin and improves the absorption of the active ingredients into the scalp.

The **Liposome technology** encapsulates the active ingredients and enables further penetration of the skin's upper surface. This enhances the absorption of the actives into the hair follicle significantly.

5. Studies on end-product

The Neofollics Hair Growth Lotion has been investigated in two seperate studies.

- In-vitro study on cell growth.
- In-vivo study on effectiveness, user-friendliness and dermatological properties.

STUDY 1:

EVALUATION ON PROLIFERATION ON HUMAN HAIR FOLLICULAR DERMAL PAPILLA CELLS

The Neofollics Lotion has been evaluated by an external laboratory on hair growth promoting potential by determining its effect on proliferation of Human Hair Follicular Dermal Papilla Cells (HFDPCs) in vitro.

In the study the in-vitro hair growth promoting potential of Neofollics was investigated by determining its effect on proliferation of Human Hair Follicular Dermal Papilla Cells (HFDPCs), which are the key cells in hair biology.

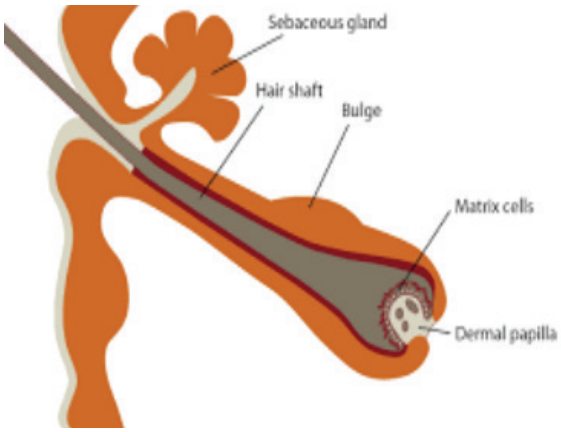


Figure 5.1. Location of dermal papilla cells in the hair follicle

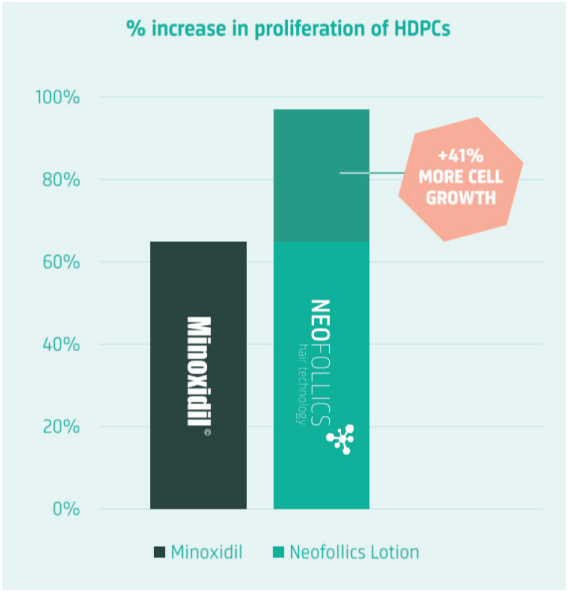
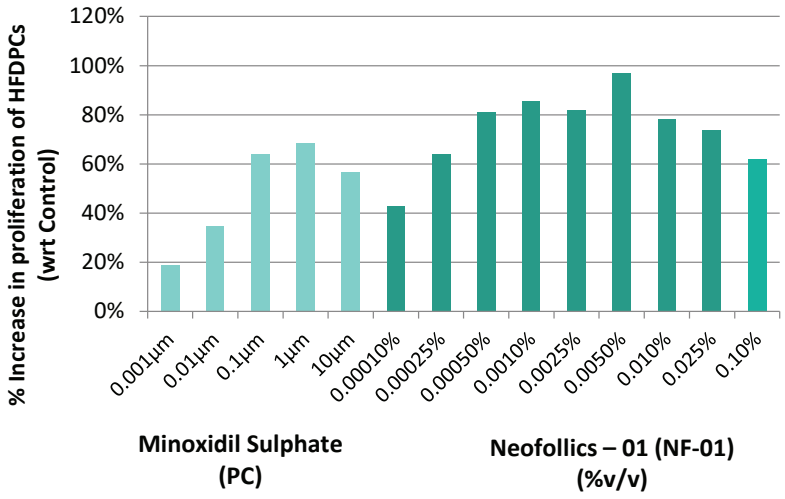


Figure 5.2. Comparison of main results Minoxidil vs. Neofollics Lotion on the proliferation of HFDPC's. group (N=90)

INCREASE IN THE PROLIFERATION OF HFDPCS

Hair follicular dermal papilla cells (HFDPCs) are widely reported as cell model to evaluate the hair-growth promoting effects of Test Items [1-6]. In the present study, hair growth promoting effect of Neofollics Lotion was evaluated in vitro using HFDPCs as reflected by the increase in cellular proliferation by BrdU assay.

To evaluate the effect on cell proliferation, HFDPCs were treated with Neofollics Lotion containing Neoxyl® for 48 h in serum starved conditions. The resultant increase in the proliferation of HFDPCs was determined by 5-bromo-2'-deoxyuridine (BrDU) incorporation Assay, that measures the mitotic activity and increase in the number of cells. It was observed that Neofollics Lotion in the concentration range of 0.0001% – 0.1% v/v demonstrated remarkable increase (up to 96.8%) in the proliferation of HFDPCs.



Sample		% Proliferation of HFDPCs (wrt Control)
Control (Untreated)		0.0
Minoxidil Sulphate (PC)	0.001µm	18.7
	0.01µm	34.5
	0.1µm	64.0
	1µm	68.3
	10µm	56.6
Neofollics (NF-01) (% v/v)	0.00010%	42.6
	0.00025%	63.9
	0.00050%	80.9
	0.0010%	85.4
	0.0025%	82.0
	0.0050%	96.8
	0.010%	78.3
	0.025%	73.7
	0.10%	62.2

Figure 5.3. Effect of Neoxyl® on the proliferation of HFDPC's compared to Minoxidil.

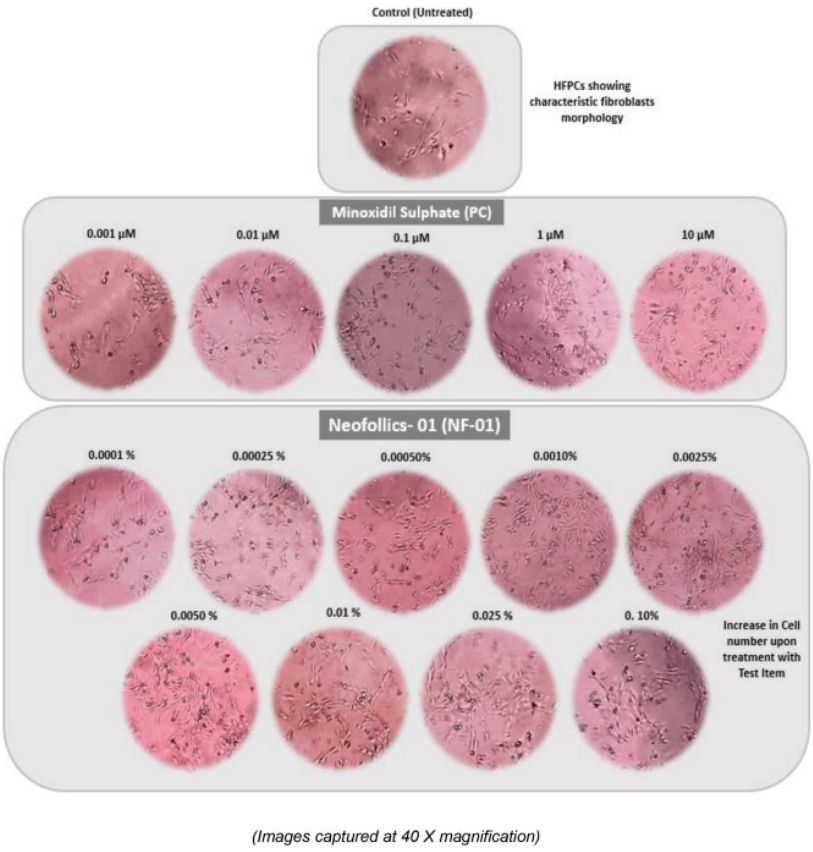


Figure 5.4. Photomicrographs representing the effect of Neoxyl® on the morphology of HFDPCs after 48 h of treatment

STUDY 2:

EVALUATION ON HAIR GROWTH AND DERMATOLOGICAL PROPERTIES BY PATIENTS WITH HAIR LOSS

The Neofollics Lotion was clinically tested and evaluated as formulation according to the same scientific evaluation methods that were used for the evaluation of Finasteride and Minoxidil, by use of self-evaluation in a questionnaire. Test subjects with Alopecia Androgenetica used the Neofollics Lotion for 3 months (T=90 +/- 3 days). They applied the Lotion as recommended; twice a day 1 ml. In total 40 subjects were included in the study.

INCLUSION CRITERIA:

- Both sexes
- Between 18 and 60
- Complaints of hair loss

MAIN OUTCOMES OF THE CLINICAL STUDY

After 90 days of usage, 75% of the test subjects experienced an increase in hair growth. And for 76% there was a reduction of hair loss. The combined effect was observed in 59% of the users: both a stimulation of hair growth and a reduction of hair loss. In total 92% of the users saw an improvement. Only 8% did not experience a visible effect.

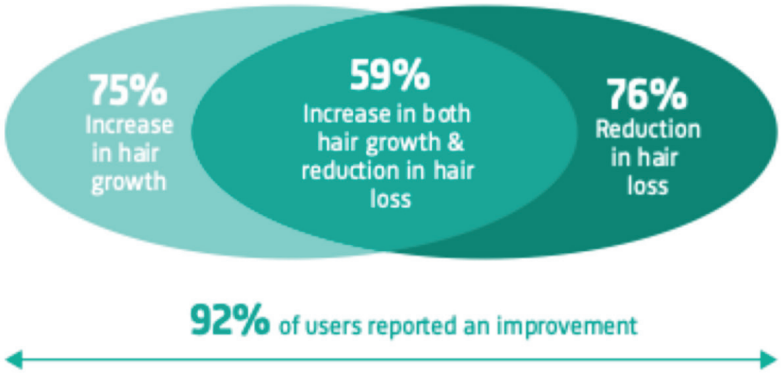


Figure 5.5. Main Outcomes

FINDINGS IN KEY EFFICACY INDICATORS

- After 90 days users have reported their findings compared to the situation before the use of the Neofollics Lotion 2 times daily. The results are summarised in figure 5.6 and 5.7.
- Over 70% of the users experienced less hair loss and an increase in hair growth.
- Over 60% of the users experenced improvement of the hair status and was satisfied with the hair growth.
- Over 50% indicated that the hair fall decreased and the hair density improved.

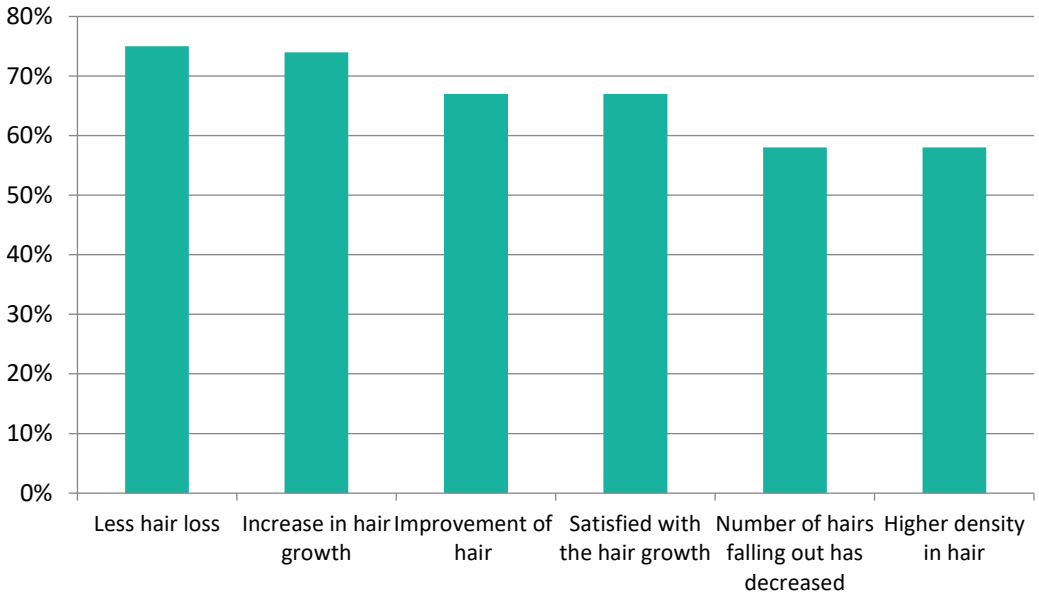


Figure 5.6. Key Efficacy Indicators

USER SATISFACTION

The Lotion was tested for user satisfaction rate. 92% of the users indicated to be satisfied with the overall usage of the Lotion. Furthermore, no side effects were reported among the users and nobody seized the treatment during the 90-day trial period due to adverse dermatological reactions and/or side effects.

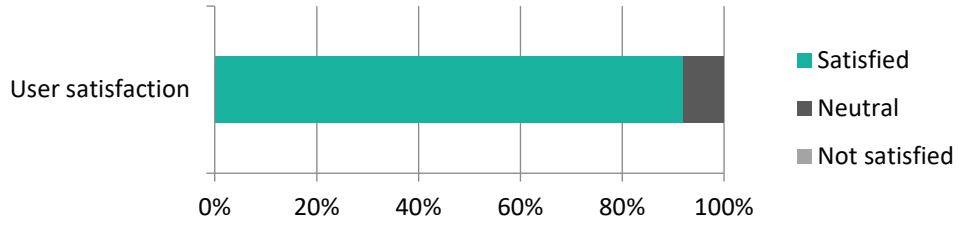


Figure 5.7. User Satisfaction

CONCLUSION

The formulation of the Neofollics Lotion is extensive, with a large number of active ingredients that have different working mechanisms on hair growth and scientifically proven beneficiary effects. The Neofollics Lotion has been evaluated both in-vitro on Human Hair Derma Papilla Cells (HDPC) and with an in-vivo (real-life) study on its efficacy as topical treatment for people with hair loss, both men and women.

A laboratory study measured the effect of Neofollics Lotion on a main hair growth indicator, the proliferation of human derma papilla cells (HDPCs). This study showed a maximum 96,8% increase in cell growth (a value of 196,8% compared to the untreated group). It indicated that Neofollics Lotion significantly promotes cell proliferation in human dermal papilla cells. For comparison, the effect of Minoxidil was also measured and showed a 68,3% increase in cell growth. The Neofollics Lotion has a +41% higher value than Minoxidil. This comparison confirms that Neofollics Lotion has the potential to be more effective.

The in-vivo (real-life) clinical trial was conducted on 40 persons during 90 days with a 2 times per day application. A majority of the users in the 90-day clinical trial reported a positive outcome on main efficacy indicators already after 90 days of treatment. The Neofollics Lotion scores best on efficacy indicators for reducing hair loss, improvement of the hair quality and satisfaction on hair growth. 92% of the users reported an increase in hair growth and/or reduction in hair growth. Furthermore, the Lotion has a user satisfaction rate of 92%. This is an important indicator since steady continuous usage of the treatment is required to obtain maximum results and therefore easy application with no adverse reactions and/or side effects is a prerequisite.

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HAIR GROWTH

The scientific approach to hair growth

The goal of Neofollics Hair Technology is to help people who are dealing with hair loss to gain control of their situation. We do this by making the latest scientific insights available to every one, developing products that stimulate hair growth effectively.

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