NEOFOLLICS LOTION – SUMMARY OF CLINICAL STUDY OUTCOMES

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.

KEY INGREDIENTS, THEIR FUNCTIONS AND EFFICACY

The Neofollics Lotion contains 3 biotechnological 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.

HAIR GROWTH MOLECULES

The lotion contains the hair growth molecules Adenosine, Vividine® and Aminexil®. These molecules have a similar effect as Minoxidil, but without the known negative side effects common in Minoxidil.

- **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.
- **Aminexil:** prevents hardening of collagen around the hair root, making the hair roots anchor themselves more firmly into the scalp, thus reducing hair loss.
- **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.

PLANT EXTRACTS

The plant extracts in the lotion have a positive effect on hair growth in multiple ways. An important

mechanism of action is the inhibition of di-hydro-testosterone (DHT). The conversion of testosterone into di-hydro-testosterone (DHT) is a major cause of (hereditary) hair loss. DHT damages the hair follicles that are sensitive to DHT, causing them to produce fewer and thinner hairs.

- 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..
- Raspberry ketone: an extract from raspberry. Raspberry ketone can increase 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.
- 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.
- 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.
- Proanthocyanidin B2 (Grape seed extract): a polyphenol from grape seeds. It allows for extending the growth phase, which provides for longer hair, and a higher density of the hair.
- 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.

CLINICAL STUDIES

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 present 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.

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.

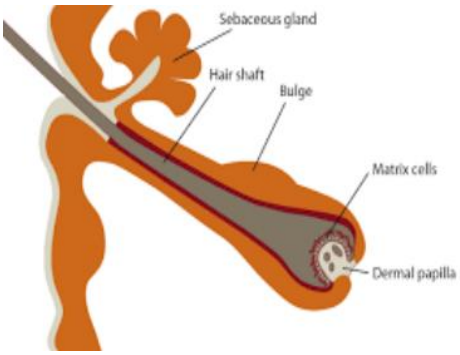


Figure 1.1. Location of dermal papilla cells in the hair follicle

To evaluate the effect on cell proliferation, HFDPCs were treated with Neofollics Lotion 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.

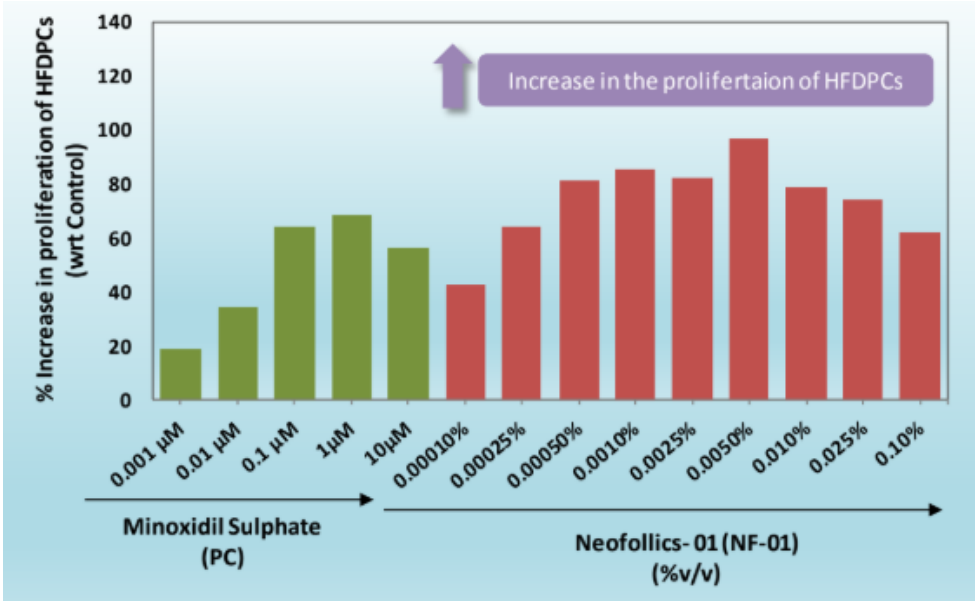


Figure 1.2. Effect of Neofollics Lotion on the proliferation of HFDPC's.

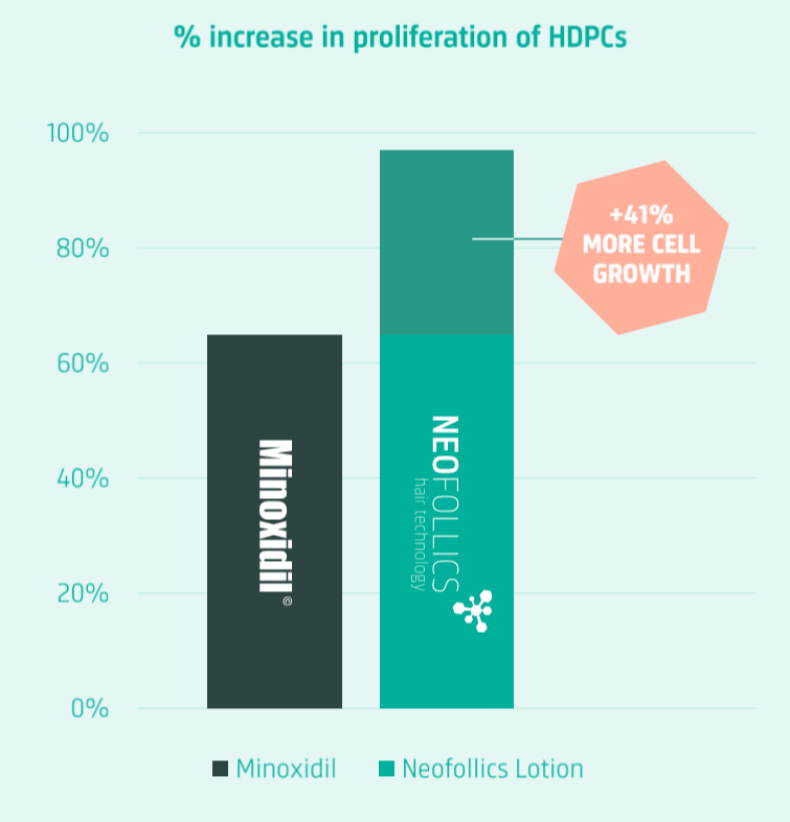


Figure 1.3. Comparison of main results Minoxidil vs. Neofollics Lotion on the proliferation of HFDPC's.

STUDY 2: EVALUATION ON HAIR GROWTH AND DERMATOLOGICAL PROPERTIES BY PATIENTS WITH HAIR LOSS

The Neofollics Lotion was clinically tested and evaluated as cosmetic 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. In total 20 subjects were included in the study.

Inclusion criteria:

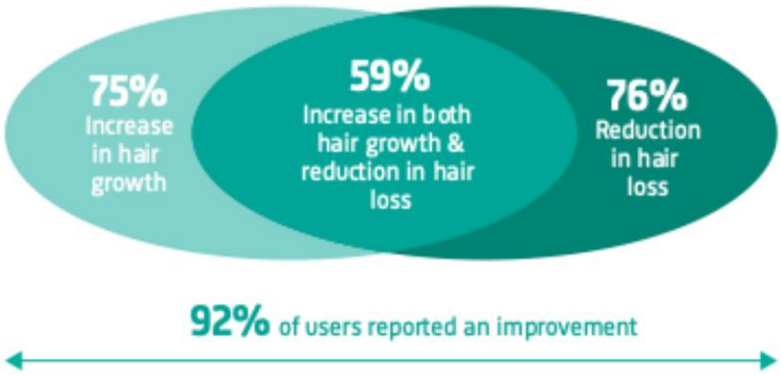
- Both sexes
- Between 18 and 60
- Complaints of hair loss

Exclusion criteria:

- Pregnancy / Breastfeeding
- Medicated or cosmetic treatments for hair loss

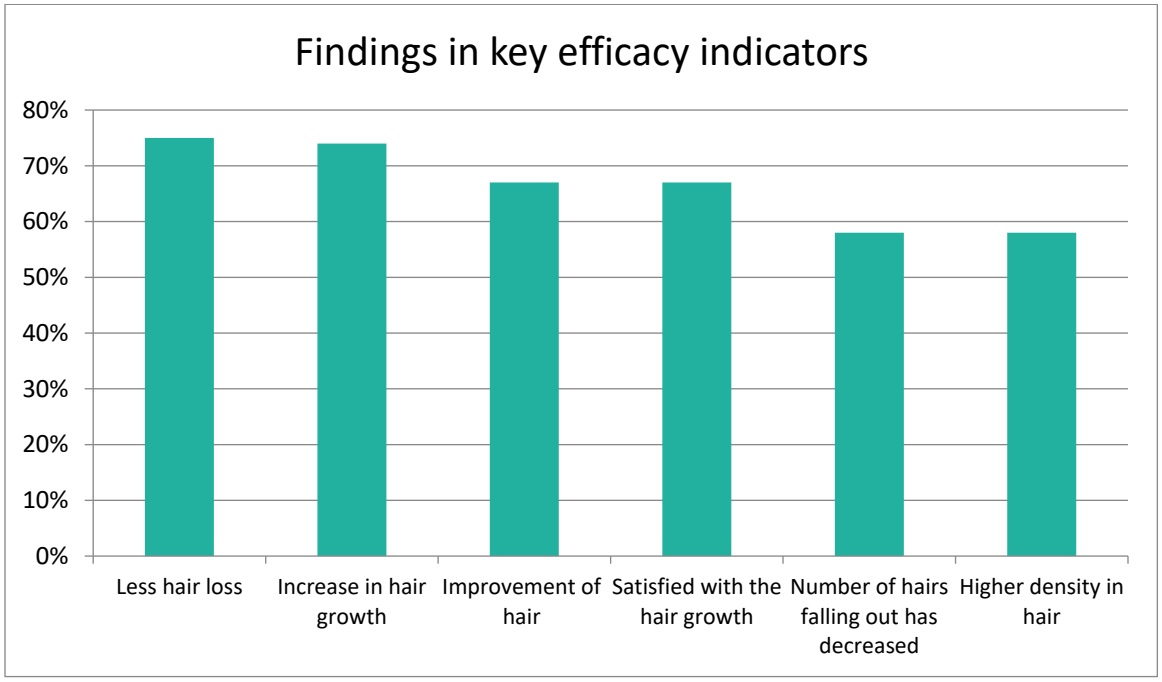
MAIN OUTCOMES OF THE CLINICAL STUDY

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.



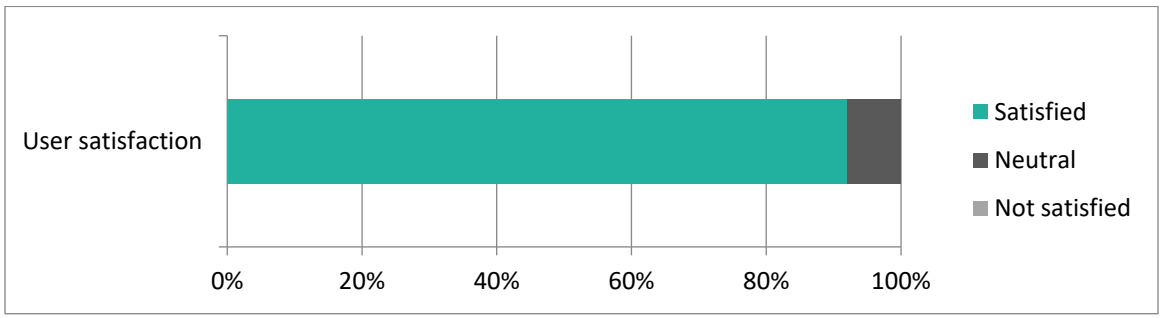
KEY EFFICACY INDICATORS

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 summarized in the table below.



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. Futhermore, 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.



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 a 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 real life clinical trial was conducted on 20 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. Futhermore, 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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