

CLINICAL STUDY REPORT

Neofollics Scalp Therapy product line



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Abstract

Background

Neofollics Hair Technology has a long history of utilizing the latest scientific breakthroughs in developing effective hair care products to combat hair problems. An internal survey conducted by Neofollics indicated that 46,5% people with hair problems experience a scalp concern such as itching, irritation, dandruff/seborrheic dermatitis and flaking of the scalp. Neofollics analysed the main scalp concerns and assessed the pathology, biochemical processes and possible treatments for these conditions in order to develop a line of Scalp Therapy products consisting of the Exfoliating Shampoo and Nourishing Mask.

Objectives

To assess the efficacy, tolerability and user satisfaction of the Scalp Therapy line in men and women with general scalp concerns such as itching, irritation, dandruff/seborrheic dermatitis and flaking of the scalp.

Methods

90 persons, both men and women within the age category 18-70 were treated with the Neofollics Scalp Therapy Exfoliating Shampoo and Nourishing Mask, applied 3 times per week for 28 days. Efficacy assessments included the degree of seborrhoea (flaking), erythema (redness of the scalp) and itching.

The test subjects used the Exfoliating Shampoo and Mask for 3 times per week for a total period of 4 weeks (12 treatments in total). All test persons underwent a symptom evaluation (seborrhoea, erythema and itching) performed by self-assessment before the start of the treatment (T=0) and after 4 weeks (T=28). Cosmetic performance indicators such as tolerability, user satisfaction and recommendation to others was also assessed.

Results

After four weeks of treatment both men and women demonstrated a significant reduction in the symptoms of seborrhoea, erythema and itching. The overall condition of the scalp was improved with a far majority of the test group. The tolerability and user friendliness were good to very good in the majority of test persons.

Conclusion

The Neofollics Scalp Therapy Line significantly improves the condition of the scalp, with a reduction of flaking/dandruff, redness and itching. These effects were already evident after 4 week. Tolerability was good and satisfaction levels were high.

1. Introduction

Neofollics Hair Technology has a long history of utilizing the latest scientific breakthroughs in developing effective hair care products to combat hair problems. An internal survey conducted by Neofollics indicated that 46,5% people with hair problems experience a scalp concern such as itching, irritation, dandruff/seborrheic dermatitis and flaking of the scalp. An unhealthy scalp can ultimately to hair loss and thinning hair. For people who already have thinning hair it is an additional concern that needs to be tackled.



Neofollics analysed the main scalp concerns and assessed the pathology, biochemical processes and possible treatments for these conditions in order to develop a line of Scalp Therapy products. The product line consists of the Exfoliating Shampoo and Nourishing Mask.

This study report includes the study results on the assessment of the efficacy, tolerability and user satisfaction of the Scalp Therapy line in men and women with general scalp concerns such as itching, irritation, dandruff/seborrheic dermatitis and flaking of the scalp. In addition, it provides background information on the main scalp concerns, causes and potential treatment and effective ingredients.

2. The Neofollics Scalp Therapy line

The Neofollics Therapy line is developed to be an effective and user friendly topical therapy to common scalp disorders and in this way to contribute to healthy hair growth. Studies show that using the right scalp treatment effectively tackles scalp problems and provides a healthy foundation for hair growth. The line consists of two products:

NEOFOLLICLS SCALP THERAPY EXFOLIATING SHAMPOO

- ✔ Nourishes the scalp
- ✔ Relieves itching and irritation
- ✔ Controls dandruff and flaking

NEOFOLLICLS SCALP THERAPY NOURISHING MASK

- ✔ Improves overall scalp health
- ✔ Relieves itching and irritation
- ✔ Controls dandruff and flaking





3. Pathology, biochemical processes and treatments

COMMON SCALP CONDITIONS

The scalp line is developed to treat and relieve the following scalp concerns:

1. Seborrheic Dermatitis
2. Dandruff
3. Eczema
4. Itching of the scalp

Other common scalp concerns that potentially may benefit from the Scalp Therapy, but are not included in the study:

5. Psoriasis
6. Lichen planopilaris
7. Folliculitis

Seborrheic Dermatitis and Dandruff are the most common scalp concerns among the target group of Neofollics. Dandruff and Seborrheic Dermatitis are correlated skin disorders: the former is a milder and more common form, tending to be dry and confined to the scalp.

Itching can be considered as first order effect of either of the first two. The main working mechanisms of the Scalp Therapy line concentrate on tackling the factors that contribute to Seborrheic Dermatitis.

The pathophysiological mechanisms of Seborrheic Dermatitis remain unclear to a certain extent. Malassezia (yeast) species are part of the normal microflora found on normal skin of 75% to 98% of healthy adults. Its role in Seborrheic Dermatitis has been supported by a positive correlation between the density of Malassezia species on the skin and the severity of Seborrheic Dermatitis.

FACTORS INVOLVED IN SEBORRHEIC DERMATITIS:

1. Altered Sebum production (hormone induced)
2. Fungal proliferation of Malassezia yeast
3. Inflammation induced hyper keratinization

SOLUTIONS FOR SEBORRHEIC DERMATITIS AS POSSIBLE THERAPEUTIC TARGET AREAS:

1. Sebum composition and reduction
2. Tackle Malassezia infection by normalizing yeast proliferation
3. Reduce inflammation by reducing the release of pro-inflammatory cytokines and normalization of the scalp
4. Restore skin barrier integrity

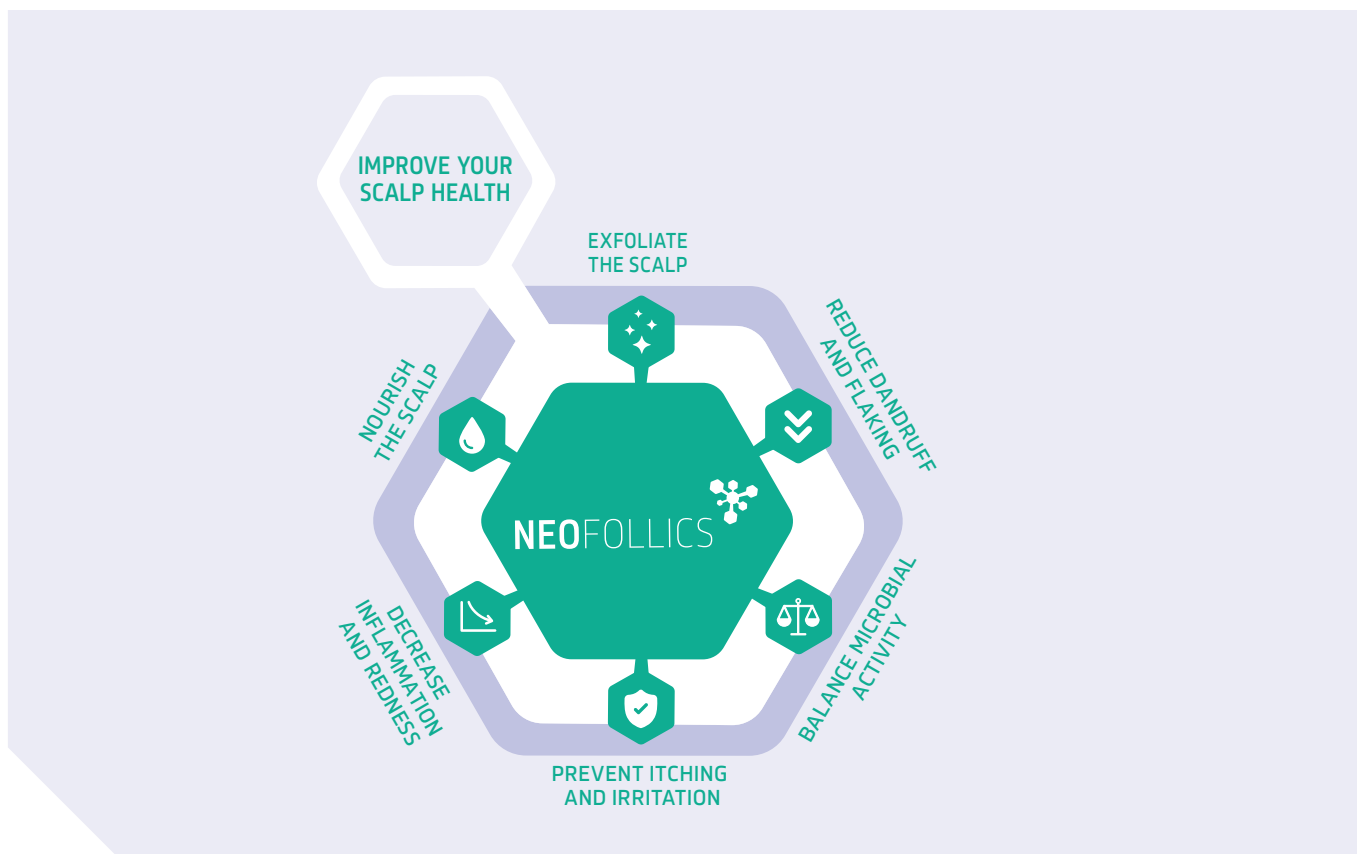
Based on the different factors involved in the causes of Seborrheic Dermatitis and Dandruff at least four main mechanisms and thus therapies can be identified. In addition, Neofollics identified two additional factors that contribute to scalp conditions:

5. Accumulation of sebum build-up and impurities
6. Scalp irritation and dryness of the scalp resulting in itching

MECHANISMS OF ACTION

In order to target the listed scalp conditions, the treatment was developed to address the following mechanisms of action:

- Normalisation of skin microbiota / proliferation of *Malassezia* yeast
- Regulation sebum production
- Reduction of flaking of the scalp
- Reduction of inflammation
- Exfoliation of excessive sebum and dead skin
- Regulation of itching and scalp irritation by nourishment of the scalp



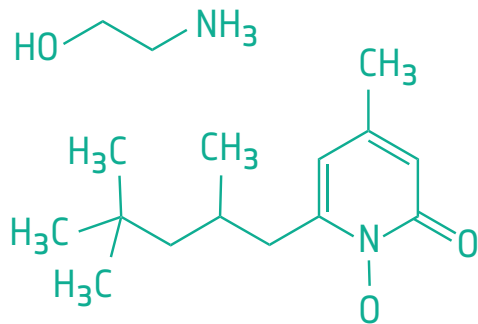
Pathways that should be addressed in a multi-approach therapy to common scalp disorders (Neofollics, 2021).



4. Key ingredients and their functions

In order to develop a multi-pathway approach a number of ingredients have been researched and selected for the Scalp Therapy line. The Neofollics Scalp Therapy line contains the following of ingredients:

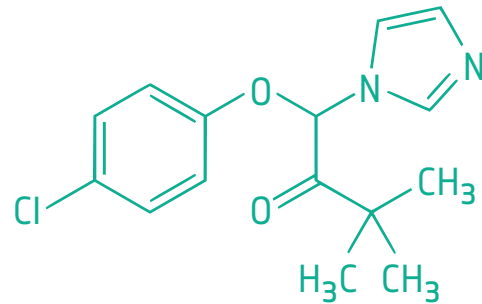
1. Piroctone Olamine
2. Climbazole
3. Witch Hazel leaf extract
4. Horse Chestnut extract
5. Licorice
6. Copper Peptides (GHK-Cu)
7. Medium Chain Triglyceride
8. Geranium
9. Rosemary
10. Lavender
11. Panax Ginseng



1. PIROCTONE OLAMINE

Known to have a fungicidal effect. Piroctone Olamine penetrates the cell membrane and forms complexes with iron ions, inhibiting energy metabolism in mitochondria. This ingredient is also used in the Neofollics Hair Growth Stimulating Shampoo. It is effective against seborrheic dermatitis and dandruff.

Furthermore, it reduces hair loss, stimulates hair growth and allows the growth of thicker hair. Studies on hair growth properties have shown that Piroctone olamine scores better than Ketoconazole in aspects of thickness of the hair and the number of hairs in the growth phase.



2. CLIMBAZOLE

Climbazole is a topical antifungal agent commonly used in the treatment of human fungal skin infections such as dandruff and eczema. Climbazole has shown a high in vitro and in vivo efficacy against Malassezia yeast that have an important role in the pathogenesis of dandruff. Its chemical structure and properties are similar to other fungicides such as ketoconazole and miconazole.

Climbazole and Piroctone Olamine have been studied as combination and was indicated to have a positive effect on itching, burning sensation, scale and tightness of the skin after 4 weeks.



3. WITCH HAZEL LEAF (HAMAMELIS VIRGINIANA)

Northamerican Virginian Witch Hazel was used by Native Americans for the treatment of superficial wounds and skin irritations. Known to have a soothing and nourishing effect to the skin and is anti-bacterial, anti-oxidant and wound healing. The natural effects of this plant are optimal for the treatment of the scalp.



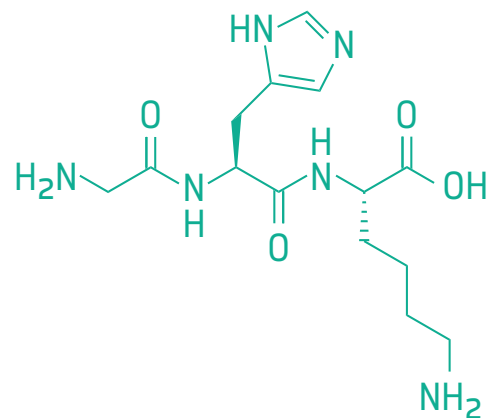
4. HORSE CHESTNUT (AESCULUS HIPPOCASTANUM)

Horse Chestnut has been shown to have one of the highest active-oxygen scavenging abilities among plant extracts. It has soothing, anti-irritating and toning properties on the skin. It is widely used in products for aged and fragile skin but also for anti-blotchiness. The fatty acids, proteins and short-chain sugars can help repair hair that is damaged by dyes, hair dryers and chemical treatments.



5. LICORICE EXTRACT

Licorice extract (*Glycyrrhizin Glabra*) is a powerful plant extract that performs well in treating Atopic dermatitis, Rosacea and Psoriasis. This is due to the acid Glycyrrhizin. This acid is anti-inflammatory and reduces redness and irritation. As anti-oxidant it protects the skin against free radicals. Another part of the extract is Glabridin, which protects from UV rays and prevents pigmentation of the scalp. It also contains Licochalcone A, which helps the skin produce higher levels of anti-oxidants and protects skin from UV damage.



6. COPPER PEPTIDE COMPLEX

Copper tripeptide-1 has an essential role in acceleration of wound healing. This compound is released during any tissue injury and promotes tissue repair. Research has documented its benefit when used in various types of wounds, including surgical, post-laser, ischemic, burns, skin transplants, hair transplants, and diabetic ulcers. Diabetic wounds healed three times faster in the presence of Copper tripeptide-1. Time to re-epithelialization is shortened.

Furthermore, Copper tripeptide-1 is active not only for primary healing but also for tissue remodeling, which is the return of injured tissue to normal architecture and function. It increases keratinocyte proliferation and normal collagen synthesis, improves skin thickness, skin elasticity and firmness, improves wrinkles, photodamage and uneven pigmentation, improves skin clarity, and tightens protective barrier proteins.



7. MEDIUM CHAIN TRIGLYCERIDES

Medium chain triglycerides contains fatty acids and has shows to have antimicrobial and antifungal effects to Malassezie species. Coconut oil, which contains numerous medium chain triglycerides, has been shown in a in-vitro study to reduce the growth of *Candida albicans* by 25%. This is a common yeast that can cause thrush and various skin infections. Coconut oil's ability to reduce yeast and bacterial growth may be due to the caprylic, capric, and lauric acid in medium chain triglycerides.



8. GERANIUM OIL

Studies on geranium oil indicated that its antibacterial, antiseptic properies make it beneficial for reducing skin irritations, skin infections and acne breakouts when applied topically. It anti-inflammatory properties also make it beneficial against scalp irritation.



9. ROSEMARY OIL

Rosemary is a perennial woody plant species, originated from the Mediterranean region, which currently can be found and cultivated in all continents as aromatic and ornamental plant; its leaves are commonly used as a condiment and also serve medicinal purposes. Its major constituents responsible for the pharmacological activities are 1,8-cineole (52.2%), camphor (15.2%), and α -pinene (12.4%).

Several studies indicate that rosemary oil nourishes the scalp and hair, has anti-inflammatory properties and acts as a hair growth stimulator. Recent studies have found that rosemary oil has an effect on fungi and bacteria.



10. LAVENDER OIL

Lavender is one of the most effective essential oils when it comes to healing skin conditions, burns and cuts. With its anti-inflammatory, antifungal, antimicrobial and detoxifying benefits, lavender essential oil can help reduce redness, soothe and calm the skin and rapidly heal minor cuts and scrapes, as well as any rashes.

Lavender oil constituents include linalyl acetate, linalool, and geraniol. It is known to be effective for the recovery of fatigue, the relaxation of stress, the growth of cells, the reproduction of skin, and alopecia areata. Among these constituents, linalyl acetate ester is effective for the relaxation of nerves, and as a tincture, linalool has antifungal effects.



11. PANAX GINSENG

Originally a Korean herb, used for skincare since medieval times. Panax ginseng is known to have a protective, anti-aging effect on the skin. It increases the moisture content and inhibit wrinkle formation.

Research on the effects of Ginseng extract include:

- reducing wrinkles and signs of aging
- promoting skin elasticity
- increasing collagen production
- reducing puffiness and inflammation
- lightening or brightening skin



5. Study on end-product

The purpose of the end-product study is to assess the efficacy, tolerability and user satisfaction of the Scalp Therapy line in men and women with general scalp concerns such as itching, irritation, dandruff/seborrheic dermatitis and flaking of the scalp.

A total group 90 persons, both men and women within the age category 18-70 years were treated with the Neofollics Scalp Therapy Exfoliating Shampoo and Nourishing Mask.

INCLUSION CRITERIA:

- Both sexes
- Between 18 and 60
- Complaints of any of the following scalp issues:
 - Flaking/Dandruff
 - Seborrheic Dermatitis
 - Itching/Irritation
 - Eczema
 - Psoriasis

NON-INCLUSION CRITERIA

- Pregnancy
- Breastfeeding
- Wounding of the scalp

TEST CONDITIONS

The test subjects used the Exfoliating Shampoo and Mask for 3 to 4 times a week for a total period of 4 weeks (12 tot 16 treatments in total). The routine was as follows:

- Rinse the hair with lukewarm water
- Apply a teaspoon (5ml) of the Exfoliating Shampoo on the scalp and hair
- Gently massage it and leave in for 3 minutes
- Rinse off with lukewarm water
- Apply a teaspoon (5ml) the Nourishing Mask on the scalp
- Leave-in the Mask, towel dry the hair and brush when needed.

All test persons underwent a symptom evaluation and evaluation of attributes related to the scalp condition:

- Seborrhoea (flaking and dandruff)
- Erythema (redness of the scalp)
- Itching and irritation
- Hydratation of the scalp
- Overall scalp health

METHOD

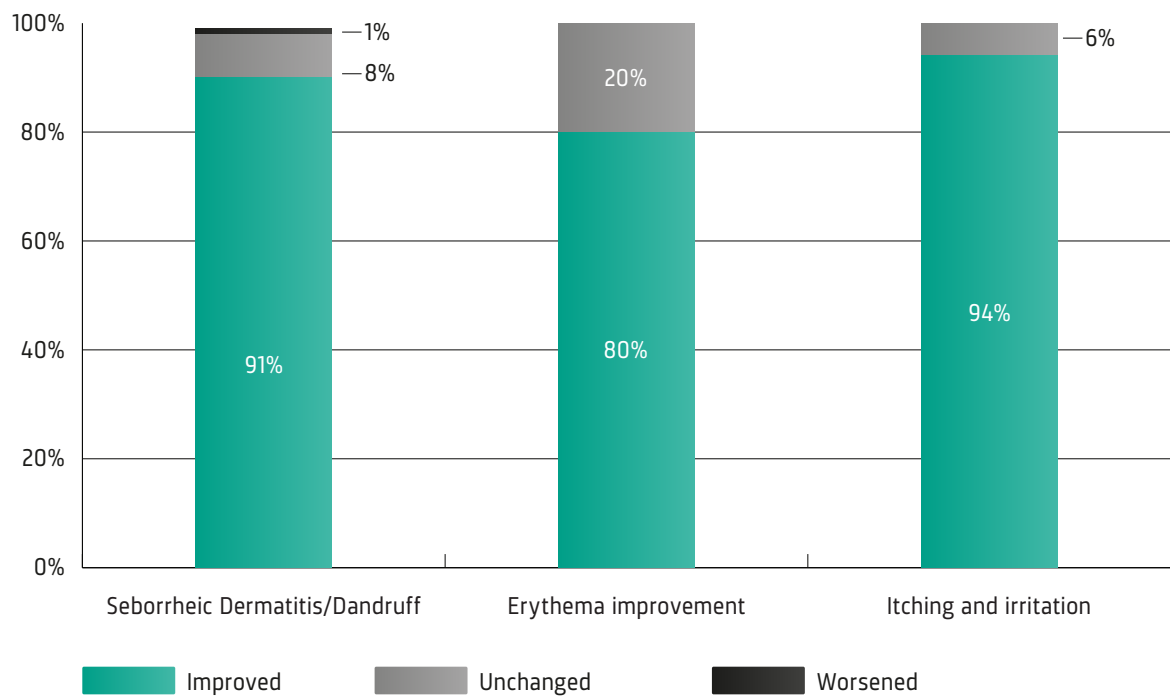
The measurement was performed by self-assessment before the start of the treatment (T=0) and after 4 weeks (T=28) based on questions with a 5 point Likert scale. As the main question, subjects were asked to which extent there had been a change in the symptoms and scalp and hair condition compared to baseline (T=0). Furthermore, photos of the T=0 and T=28 situation were made in order to review the symptom evaluation.

In order to assess the overall performance and user friendliness, the following performance indicators were also included:

- Tolerability
- User satisfaction rate
- Recommendation to others (would recommend in %)

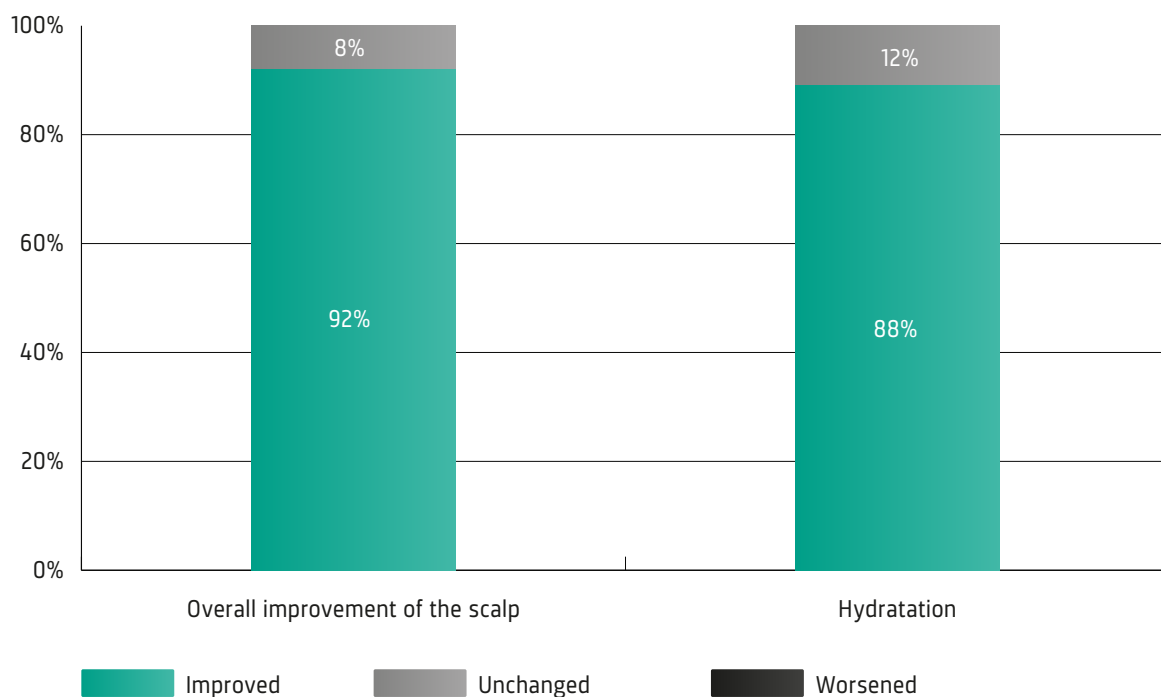
RESULTS ON SEBORRHOEA, ERYTHEMA AND ITCHING

- Seborrhoea improvement (reduction of flaking and dandruff on the scalp) in 91% of the persons.
- Erythema improvement (reduction in redness of the scalp) in 80% of the persons.
- Reduction in itching and irritation of the scalp among 94% of the persons.



RESULTS ON ON OVERALL IMPROVEMENTS OF THE SCALP AND HYDRATATION

- 92% of the test persons indicated an overall improvement of the scalp after 4 weeks of using the Scalp Therapy products.
- 88% of the test persons indicated an improvement in the hydration of the scalp



RESULTS ON TOLERABILITY, USER SATISFACTION AND RECOMMENDATION TO OTHERS

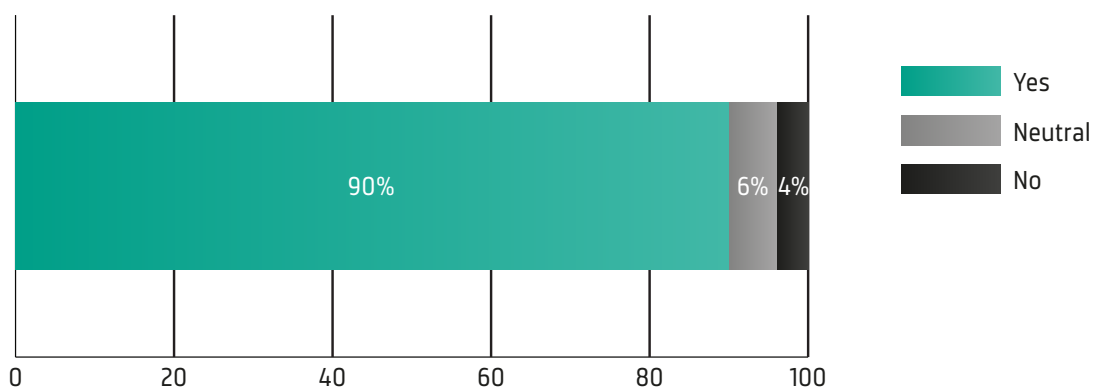
Tolerability

The Tolerability of the Exfoliating Shampoo in combination with the Nourishing Mask was good. No one ceased the treatment or lowered the intensity of the treatment due to adverse effects or uncomfotability. No adverse effects were registered.

User satisfaction of the whole treatment

96 % of the users are satisfied with the Neofollics Scalp Therapy line. The only comment received was that people needed to get used to the exfoliating nature of the shampoo or were not accustomed to using a leave-in mask. 90% of the users would recommend it to others.

Would recommend on others



Overall user satisfaction

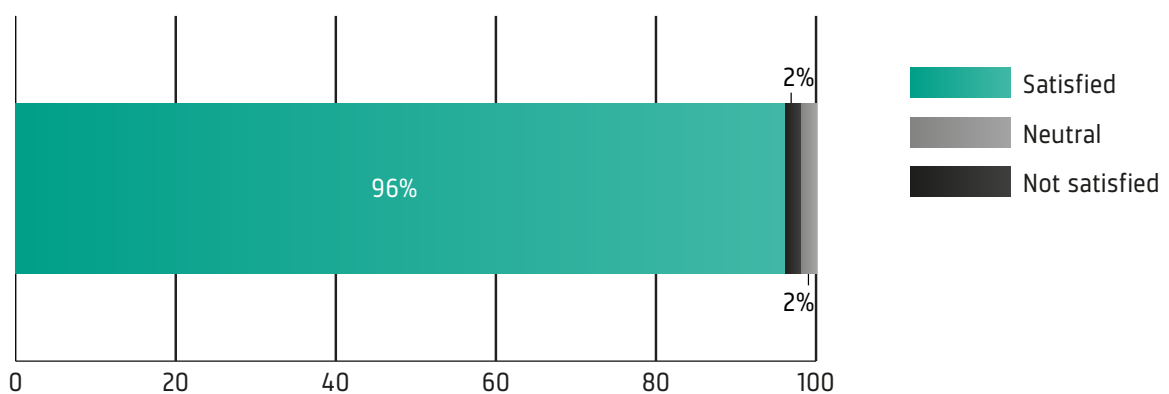


Photo assessment (before and after)

Improvement of scalp condition, before and after four weeks of local treatment with Neofollics Scalp Therapy.



Fig 5.1. Improvement in the scalp condition, decrease of dandruff/flaking and improvement of hair density.



Fig 5.2. Improvement in the scalp condition, decrease of dandruff/flaking, erythema.



Fig 5.3. Improvement in the scalp condition, decrease of dandruff/flaking, erythema and improved hair density in AA affected area.

CONCLUSION

The efficacy of the Neofollics Scalp Therapy Line was clinically tested and evaluated. Test subjects with complaints of a scalp concern were selected and tested both the Exfoliating Shampoo and the Nourishing Mask as combination treatment for a period of 28 days. They used the products as recommended, three to four times per week. In total 90 subjects were included in the study.

After 28 days of usage the following results were found:

- Seborrhoea improvement (reduction of flaking and dandruff on the scalp) in 91% of the persons.
- Erythema improvement (reduction in redness of the scalp) in 80% of the persons.
- Itching and irritation improvement in 94% of the persons
- Hydratation of the scalp was improved in 88% of the persons.
- Overall improvement of the scalp in 92% of the persons

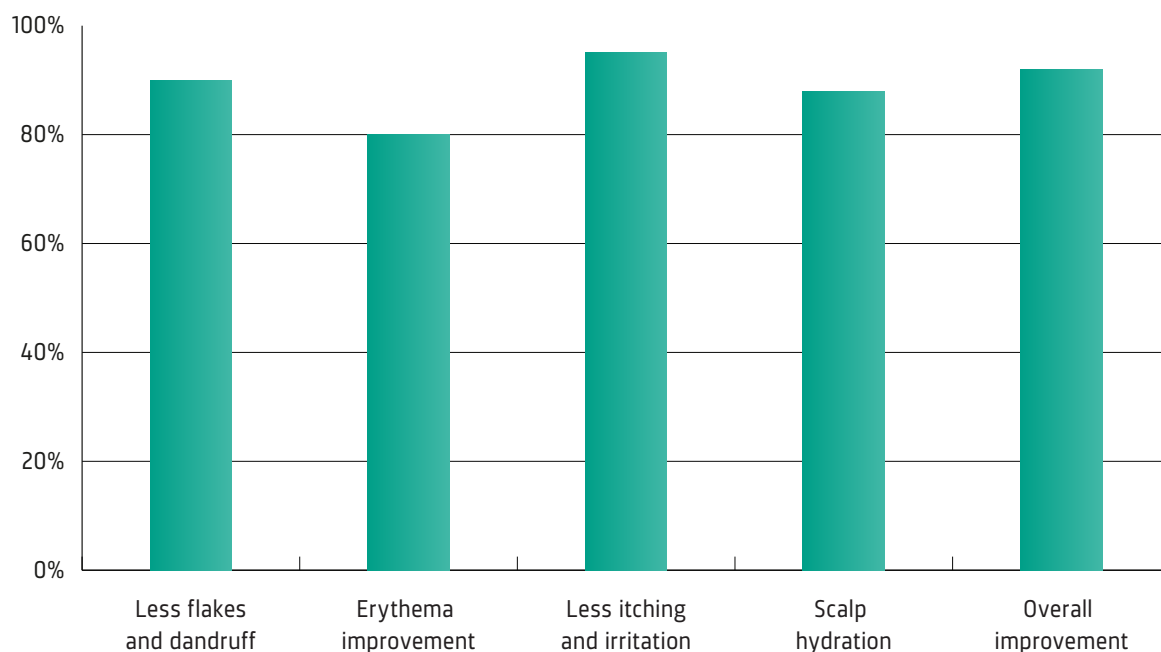


Fig 5.4. General conclusions over the total test group (N=90)

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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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