In vivo study of novel topical solution for patients with seborrheic dermatitis.

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Introduction

Seborrheic dermatitis (SD) is a common chronic recurrent inflammatory disorder with prevalence of 3-5% of population with a slight male predominance. It is one of the most common skin dermatoses. SD manifests as erythematous patches with white to yellow greasy scale often associated with pruritus.

The aim of this study was **to test safety and efficacy of a topical formulation in SD treatment**. The tested solution (14012) contained **biotin, burdock extract and zinc PCA salt, that have seboregulatory properties, piroctone olamine as an antibacterial and anti-fungal agent, prebiotic oligosaccharide (inulin) that supports balanced growth of skin microbiota, and citrus extract that provides vitamins and flavonoids.**

Methods

The solution was tested *in vivo* in a group of 20 subjects (15 women and 5 men) aged 20 – 58 with **diagnosed seborrheic dermatitis, chronic pruritus, seborrhoea, flaking and erythema of the scalp**. Subjects applied the product on the scalp and body SD lesions 1-2x/day for 3 weeks. All participants assessed the solution in satisfaction survey.

Ten of the subjects took part in instrumental assessment. Two squares (1x1 cm) were marked on each subject's head, washed with 38°C water and dried. **Skin erythema and sebum levels were measured** at baseline and after the assigned time of product usage with Miravex Antera 3D and Sebumeter SM 815, respectively. Digital **dermatoscope and trichoscope** were used to examine scalp lesions.

Another group of 10 subjects (aged 24-65) took part in a pH test. **Scalp pH was measured** before and 30 minutes after a single application of tested solution using Skin-pH-Meter Courage-Khazaka.

Conclusion

The results of this in vivo study confirmed the expected efficacy of the product that was based on selected active ingredients. Improvement of skin condition in subjects with seborrheic dermatitis was measured instrumentally and confirmed by study participants in satisfaction survey.
In conclusion, the tested cosmetic product can be recommended for individuals suffering from SD and was especially effective in scalp lesions.

Results

after long term application, n = 10		
sebum level		
baseline	after 3 weeks	change
208	185	**-11%**
erythema level		
baseline	after 3 weeks	change
1,265	1,096	**-13%**

after one application, n = 10	
pH	
baseline	30 min after product application
6,9	**5,5**

Figure 1. The results of scalp biometric measurements. Ten patients used solution 14012 for 3 weeks. **Decrease of sebum level by 11% and lowering erythema intensity by 13% were observed.**

Another group of subjects had scalp pH measured 30 min after a single product application. **The average pH value decreases from the neutral 6,9 to the physiological value of 5,5.**

Subjects' self-assessment, n=20	% of subjects
soothes itching, redness, flaking of the skin and excessive sebum production	89%
immediately soothes the skin	83%
reduces skin peeling	78%
reduces symptoms of seborrheic dermatitis	78%
inhibits excessive hair oiliness	72%
reduces hair loss	61%

Figure 2. Selected results of patients' assessment after 3 weeks use of solution 14012. The table presents the percentage of subjects who confirmed the listed effects of the product.
89% of respondents confirmed **reduction in itching, erythema, skin flaking and sebum level** shortly after product application. The majority of participants also declared **reduced hair loss** (61% of subjects).

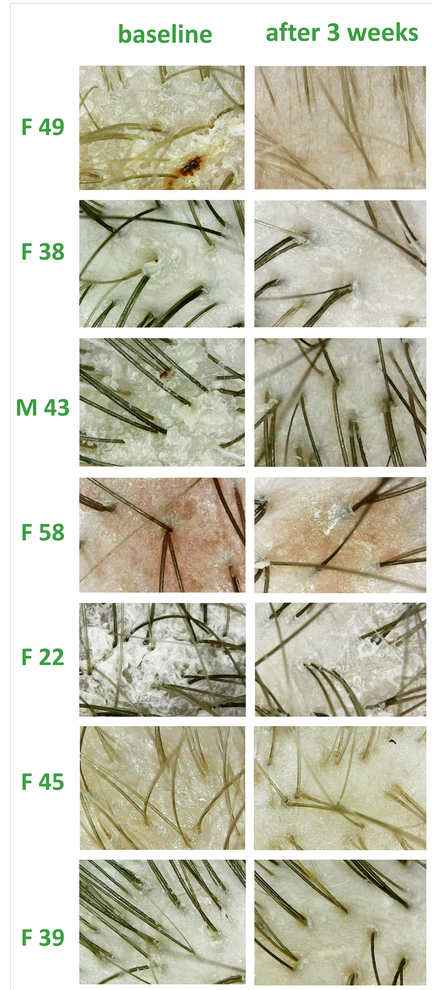

Figure 3. Selected trichoscopy images taken at baseline and after 3 weeks of applying solution 14012 on the scalp.
F - female, M - male, the numer indicates subjects' age.

The tested product significantly decreased dandruff scales, erythema and seborrhoea.