**Results of the clinical study of Ecnaclyn (lactoferrin) in patients with acne vulgaris**

A lot of teenagers, but also adults is suffering from acne vulgaris, the increased formation of sebum and subsequent bacterial colonization of the skin (mainly by *Propionibacterium acnes*). This results in the keratinization of the cells and obstruction of the sebaceous glands, redness of the skin and formation of comedones and impurities.

In this document we summarize the results of lactoferrin administration in patient suffering from acne papulopustulosa (grade I-IV). We evaluate an effect on both non-inflamatory and inflammatory acne lesions, on tolerance of a preparation and on satisfaction of patients.

**What are the main mechanisms of action of lactoferrin (Praventin™)?**

One of the crucial factors underlying the development of acne is a bacterium called "Propionibacterium acnes". Antimicrobial activity of **Praventin™** against these bacteria has been proved by numerous experiments in vivo and in vitro.

It has both a **bacteriostatic** /inhibiting the growth and reproduction of bacteria/ and **bactericidal** /killing/ effect. Bacteriostatic effect is mediated by scavenging of iron ions, representing important bacterial growth factor, from the mucosal surfaces, the bactericidal effect is mediated by the direct damage of the bacterial cellular wall and liberation of lipopolysaccharides.

Other mechanism of action of **Praventin™** to fight acne is a direct interference with activity of the immune system and influence on immune response /modulation of production of interferon γ, interleukin Ib, interleukin 6, tumour necrosis factor α (TNF-α), interleukin 4, 5 and 10./

The promotion of antioxidative defence of the complexion /reduction of lipid peroxidation/ and binding of A lipids from the lipopolysaccharides from the disintegrated bacteria is also indispensable.

# Results of surveillance of Ecnaclyn made by Walmark

Patients with diagnosed acne over 10 years of age were included in the study. The patients used 1 tablet of Ecnaclyn daily for 8 weeks and underwent three examinations – when entering the study, three weeks later and after eight weeks of application. At each visit the number of comedones was evaluated (closed non-inflammatory white pimples or open black comedones) and of papulopustules (inflammatory lesions – pimples). On closing the study, the patients evaluated their satisfaction with the product using a 1-5 degree scale (1 – very satisfied, 5 – unsatisfied) and also potential adverse reactions were recorded during the application. The study included 25 patients.

As early as 3 weeks later, the number of both comedones and papulopustules statistically significantly decreased  from the average number of 17.3 to 11.9 and from 21.6 to 9.3  respectively (p<0.05) which after 8-week application further statistically significantly decreased to 5.4 and 5.2 respectively (p<0.05).

Final subjective evaluation of the patients´ satisfaction with Ecnaclyn using a 1-5 degree scale (1 best, 5 worst):

degree 1: 80%, degree 2: 12% and degree 3: 8%.

During the product application, no study participants encountered any adverse reactions.

Graph1: Average number of comedones and papulopustules by the individual visits

Graph 2: Final subjective evaluation of the patients´ satisfaction with ECNACLYN using a 1-5 degree scale

Picture: Examples of stutus before and after 8-week consumption of ECNACLYN

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| 1. Status before consumption
 | 1. Status after consumption
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| C:\Users\heinrich\Documents\Acneon\Semanová Martina_83_16.2.09-pred acneon (1).JPG | C:\Users\heinrich\Documents\Acneon\Semanová Marta_83_15.4.2009-ukonceni acneon.JPG |
| C:\Users\heinrich\Documents\Acneon\Smrž Tomáš_92-24.2.09-pred acneon.JPG | C:\Users\heinrich\Documents\Acneon\Smrž Tomáš_92-21.4.2009-ukončení acneon (2).JPG |
| C:\Users\heinrich\Documents\Acneon\Heřman Pavel_90-20.3.2009-pred acneonem.JPG | C:\Users\heinrich\Documents\Acneon\Heřman Pavel_90-19.5.2009-ukončení acneon (1).JPG |
| C:\Users\heinrich\Documents\Acneon\Pavlíček Ondřej_88-11.3.2009-pred acneonem (1).JPG | C:\Users\heinrich\Documents\Acneon\Pavlíček Ondřej_88-6.5.2009-ukončení acneon (3).JPG |

## Conclusion

During Ecnaclyn application, the number of comedones and papulopustules in the acne patients statistically significantly decreased as early as after 3 weeks and after 8-week use it further statistically significantly dropped. According to their evaluations, 80% of the patients were very satisfied with the product.

Ecnaclyn has been checked by the Swedish Medical Agency.

More informations in Swedish are available at [www.ecnaclyn.se](http://www.ecnaclyn.se).

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