

Fact Sheet Acne - Microos Staphefekt SA.100 (Gladskin)

Acne is a common inflammatory skin disorder in adolescents, with symptoms including comedones, papules, pustules and sometimes cysts. Persistence of symptoms in adult life is seen in about 50% of the people. Acne primarily affects the face, negatively influencing the quality of life.^{1,2,3}

Although the exact causes of acne are not fully understood, the bacterium *Staphylococcus aureus* can cause (secondary) infection of the skin lesions, leading to inflammatory symptoms like redness, itch, pain and swelling.

Current therapies for acne include combinations of retinoids, hormonal therapy and antibiotics. Because of the chronic nature of the disorder, treatments should be safe to use over a longer period of time. Especially with oral retinoids, side effects are of concern. With antibiotics, prolonged use leads to antimicrobial resistance of bacteria. Therefore, the Global Acne Alliance guidelines recommend limiting the duration of antibiotics.¹

Staphefekt SA.100 is an endolysin, a targeted antibacterial enzyme. Contrary to antibiotics, it kills only *S. aureus*, leaving the beneficial bacteria intact. And by targeting essential parts of the bacterial cell wall of *S. aureus*, resistance is neither observed nor expected.^{4,5,6} As an active ingredient in emollients, Staphefekt is therefore suitable for long-term daily use as suppression therapy of *S. aureus* on the skin.⁷

In a questionnaire-based study by prof. Pasmans, pediatric dermatologist at the Erasmus Medical Centre Rotterdam, Staphefekt in an emollient (Gladskin) was applied on the skin of 57 patients suffering from acne. After one month of daily use, patients experienced significantly less severity of comedones, papules, pain and cysts (figure 1). Also the number of pustules had dropped significantly (figure 2). The quality of life was enhanced, as measured by a scientific disease specific score, the Cardiff Acne Disability Index (CADI).^{7,8}

Since Staphefekt targets only *Staphylococcus aureus*, the positive effect of Gladskin on symptom severity suggests a role for this microorganism in acne. People will always be challenged with *Staphylococcus aureus*, as it is often present on our body and in our environment. In some of us, colonization with this bacterium eventually leads to inflammation, as is the case with secondary infection of acne. With Staphefekt, the first *targeted* antibacterial compound is available for daily use as maintenance therapy, to intervene before colonization can progress and lead to infection.

Decreased acne severity after Gladskin

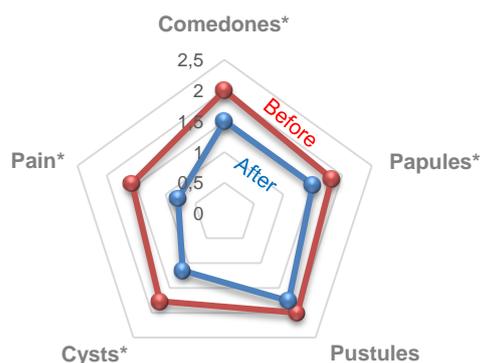


Figure 1. Acne severity was measured before and after Gladskin use in 59 patients (average use 37 days) with the Global Acne Severity Score (GEA). The overall disease severity decreased significantly after Gladskin (GEA score, $p < 0.001$; and individual symptom scores $*p < 0.02$).

Reduction of pustules after Gladskin

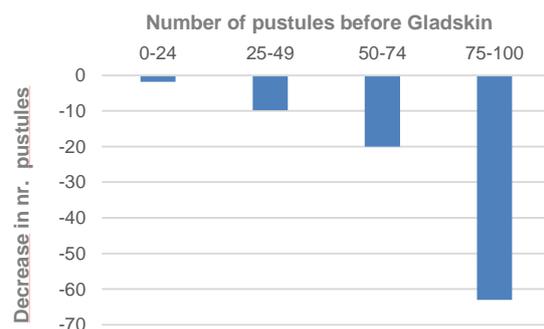


Figure 2. The number of pustules was counted before and after use of Gladskin acne gel or cream. The number of pustules decreased significantly ($p = 0.001$).



The first case study was observed in an adult man suffering from acne, diagnosed by his GP since his adolescence. Before starting treatment with Staphefekt, the presence of *S. aureus* in the skin lesions was confirmed (left). After 6 weeks use of Staphefekt twice daily, he reported less inflammatory symptoms of redness, swelling, and itch (right).

References

1. Thiboutot D, Gollnick H, Bettoli V, Dreno B, Kang S, Leyden JJ, et al. New insights into the management of acne: an update from the Global Alliance to Improve Outcomes in Acne group. *J Am Acad Dermatol*. 2009 May;60(5 Suppl):S1-50.
2. Goulden V, Stables GI, Cunliffe WJ. Prevalence of facial acne in adults. *J Am Acad Dermatol*. 1999 Oct;41(4):577-80.
3. Dunn LK, O'Neill JL, Feldman SR. Acne in adolescents: quality of life, self-esteem, mood, and psychological disorders. *Dermatol Online J*. 2011;17(1):1.
4. Nelson DC, Schmelcher M, Rodriguez-Rubio L, Klumpp J et al. Endolysins as antimicrobials. *Advances in Virus Research*. 2012. 83(7):299.
5. Herpers BL, Badoux P, Totté JEE, Pietersma F, Eichenseher F, Loessner MJ. Specific lysis of methicillin susceptible and resistant *Staphylococcus aureus* by the endolysin Staphitekt SA.100. European Congress of Clinical Microbiology and Infectious Diseases (ECCMID); Barcelona2014.
6. Herpers BL, Badoux P, Pietersma F, Eichenseher F, Loessner MJ. Specific lysis of *Staphylococcus aureus* by the bacteriophage endolysin Staphitekt SA.100: *in vitro* studies and human case series. *Antibiotic alternatives for the new millenium*; London, 2014.
7. Herpers BL, Offerhaus M. Data presented at the Royal Society of Medicine Medical Innovation Sping Summit 2015, London. Available at <https://www.staphitekt.com/en/newspublications>.
8. Totté JEE, Pasmans SGMA. Manuscript in preparation. Data available at Microeos.