**Probactiv™ throat**  
– supplement the normal flora in the throat

**What is the mode of action of Probactiv™ throat?**  
Probactiv™ throat contains selected bacteria that supplement the normal flora of bacteria in the throat. A barrier of normal flora in the throat can give better protection against harmful bacterial infections of the throat and inner ear.

**When should Probactiv™ throat be used?**  
Probactiv™ throat can be used when symptoms of a cold appear or as a preventative measure in cold season. Probactiv™ throat can also be used after antibiotic therapy of upper respiratory infections.

**How is Probactiv™ throat used?**  
Probactiv™ throat can be mixed in cold drinks, gargled and swallowed, or sprinkled over warm, not hot food.

**What are the active substances in Probactiv™ throat?**  
*Streptococcus sanguis* 89a & *Lactobacillus rhamnosus* LB21

**How is Probactiv™ throat stored?**  
Unopened sachets can be kept at room temperature.

**What is the shelf life of Probactiv™ throat?**  
Unopened sachets: are active up to 2 years at room temperature.

**Registration**  
Food supplement/medical food

**Benefits of Probactiv™ throat**

1. Probactiv™ throat contains an abundance of normal bacteria for the throat that can interfere with pathogenic bacterial in the upper respiratory tract.
2. Probactiv™ throat contains alpha-hemolytic streptococci and lactobacilli that in studies have shown to have a good inhibition effect on pathogenic bacteria. Alpha-hemolytic streptococci and lactobacilli supplement the normal flora in the throat and can interfere with the growth of pathogenic bacteria in the throat, which is especially important after antibiotic therapy.

**Patents**

SE-21036341 valid until and including 2028  
WO2007108764 valid until and including 2026

**Clinical overview**

The aim of an antibiotic treatment is to eliminate pathogenic bacteria. A negative effect of antibiotics is that they also eliminate the “good” bacteria, i.e. the normal flora. After finishing an antibiotic therapy the patient may easily be re-infected. This may be caused by the elimination of the normal flora in the throat, allowing pathogenic bacteria to multiply without any competition, thus creating a new infection. Probactiv™ throat adds natural bacteria to the upper respiratory tract which can interfere with pathogenic bacteria during the time it takes for the body to rebuild the normal flora. Studies on individuals that have received antibiotic therapy have shown that those who are easily re-infected after treatment often lack normal flora in the throat, compared to a control individual. Adding a normal flora to the throat can reduce the number of relapses of infections in the upper respiratory tract such as tonsillitis.

**Research**

*Streptococcus sanguis* 89a has been studied in a lot of studies, and *Lactobacillus rhamnosus* LB21 too. The results from some of the studies are described below.

**Fewer relapses of tonsillitis after treatment with alpha-hemolytic streptococci**  
130 patients with recurrence of group A beta-hemolytic streptococci (GAS) and clinical signs of tonsillitis were enrolled in the study. It was a randomized, placebo-controlled and double-blinded multi-center study. The patients were on antibiotic therapy for 10 days followed by 10 days with alpha-hemolytic streptococci or placebo treatment. Patients who received antibiotic therapy for at least 9 days and used the spray for at least 5 days were included in efficacy analysis. Patients who had a relapse within the first 5 days after start of treatment were classified as “early relapse”. The total bacterially verified clinical relapses in the alpha group (n = 51) was 2% and the placebo group (n = 61) 23% of the population who used the spray for at least 5 days (p = 0004) (Figure 1). If “early relapse” are included, the difference is reduced (p = 0064). Both treatments were well tolerated. The conclusion was that administration of alpha-hemolytic streptococci for at least 5 days significantly reduces the risk of tonsillitis recurrence. (11)

342 patients with tonsillitis and presence of group A beta-hemolytic streptococci (GAS) were enrolled in another study. It was a randomized, placebo-controlled and double-blinded multi-center study. The patients were on antibiotic therapy for 10 days followed by 10 days with alpha-hemolytic streptococci or placebo treatment in a 2:1 ratio. Status of the throat, throat culture and adverse events were examined up to 75 days after treatment. After 22 days the baterially verified relapses were 13% in the alpha group (n = 189) and 15% in the placebo group (n = 93). After 45-75 days 19% in the alpha-group and 30% in the placebo group had had a relapse (p = 0037). Moreover, at the last visit 5% of the patients in the alpha group were healthy carriers of GAS, while the corresponding figure was 12% in the placebo group (p = 0029). Both treatments were well tolerated. The conclusion was that long-term treatment with alpha-hemolytic streptococci can prevent the recurrence of GAS tonsillitis for a long time. (13)

**Otitis media and general health improvement**

130 children aged 6 months-6 years with a predisposition for otitis media were enrolled in a double-blinded, randomized and placebo-controlled study; 108 of these could be monitored throughout the study period (three months). After antibiotic treatment the children used either nasal spray with alpha-hemolytic streptococci or placebo for 10 days. After 3 months 42% of the subjects who received the spray with alpha-streptococci were healthy and had a normal tympanic membrane, the corresponding figure was 22% in the placebo group (p = 0.02) (Figure 2). The conclusion was that the selected bacteria with the ability to inhibit growth of normal otitis pathogens may reduce the recurrence of acute otitis media and secretory otitis media in children. (15)
In another study it was evaluated whether milk with added probiotic bacteria and fluoride had an effect on caries development and the general health of preschool children. Children between 1-5 years (n = 248) from 27 units in 14 day care centers in the northern Sweden were included in the study. The centers were randomized to two parallel groups: children in the active group served in 150 ml of milk with added Lactobacillus rhamnosus LB21 (10^9 CFU / ml) and 2.5 mg of fluoride per liter during lunch, while the control group received regular milk. The double-blinded trial lasted for 21 months (weekdays only) and data were collected through clinical examinations and questionnaires. At study entry, the amount of caries was 0.5 DMFS (decay index) in the active group and 0.6 in the control group. After 21 months the corresponding number was 0.9 and 2.2 (p <0.05). In the children who participated throughout the study period there were fewer days with antibiotic therapy (p = 0.06) (Figure 3). The conclusion was that milk supplemented with fluoride and probiotics reduced the caries increase in children, and had additional beneficial effects on health. (17)

Scientific studies on Streptococcus sanguis 89a and Lactobacillus rhamnosus LB21:

**In vitro studies**

**Clinical studies**
12. Roos K, Lind L, Grahn Håkansson E. Perianal streptococcal dermatitis. The possible protective role of alpha-


