



ToothGuard &
ToothGuard Junior
with BLIS M18™

FreshBreath Kit
with BLIS K12™





THE MOUTH

- + More than 700 strains of bacteria have been detected in the mouth – most of us host between 30 and 70 at any one time.
- + Most are harmless, some have a protective role.
- + **There are a few that are particularly damaging:**

Streptococcus mutans lives in the mouth and feeds on the sugars and starches we eat. As a by-product, it produces enamel-eroding acids, which make streptococcus mutans the main cause of tooth decay in humans.

Porphyromonas gingivalis is usually not present in a healthy mouth, but when it does appear, it has been strongly linked to periodontitis.

ORAL PROBIOTICS

- + Probiotics (pro=for, bios = life) are beneficial live bacteria that help the body deal with pathogenic (bad) bacteria.
- + Most people think of their gut when they think of probiotics, however oral probiotics also play an important role in overall health. Whether oral or gut, probiotics are live microorganisms that give us health benefits when we take them, especially when taken regularly.
- + Harmful organisms often enter your body through your mouth or nose, so oral probiotics are an excellent first line of defence for the mouth and throat. Oral probiotics remain in the mouth and work there to promote a balanced microflora and help maintain normal healthy oral bacteria.



ADVANCED ORAL PROBIOTICS

- + BLIS K12 and BLIS M18 are the world's first advanced oral probiotics and are proven to support a healthy immune response, through maintaining a healthy balance of good bacteria.

WHY ARE THEY 'ADVANCED'?

- + Probiotics work primarily by 'crowding out' the bad bacteria. Its called competitive exclusion; the good bacteria crowd out the bad preventing them from gaining a foothold and growing to levels which would cause us harm.
- + BLIS Probiotics have added capability - they produce bacteriocin-like Inhibitory substances (blis) which are potent antimicrobial peptides – not only do they crowd out, they also inhibit the growth of bad bacteria.

BLIS K12™

- + **Streptococcus salivarius** K12 (BLIS K12™) is the world's first bacterial replacement probiotic specifically derived from the human oral cavity and designed for use in the oral cavity.
- + The BLIS K12 strain was identified following a large study of school children, in which **S. salivarius** was identified as one species that appeared to provide protection against the pathogenic bacteria **S. pyogenes**, the causative agent of Strep sore throat. As a result of this study the K12 strain was isolated from a child with no history of sore throats.
- + It was found that the BLIS K12™ strain has the broadest spectrum of anti-microbial activity, known as bacteriocin-like inhibitory substances (BLIS), of all **S. salivarius** characterized to date.





BLIS K12 & BAD BREATH

- + Oral malodour, also called halitosis, afflicts a significant proportion of the adult population and is of common interest due to its compromising influence in social and working environments.
- + Most halitosis oral malodour compounds are by-products of the metabolism of certain species of oral bacteria, mainly those on the dorsum of the tongue. These compounds consist of VSC (volatile sulphur compounds), valeric acid, butyric acid and putrescine.
- + Current treatments focus on the use of chemical or physical antibacterial regimens to reduce the numbers of these bacteria. The treatments typically provide only short-term relief because the offensive bacteria quickly recover after treatment is stopped.
- + Clinical studies have shown that BLIS K12 is able to inhibit the growth of the bacteria that are most closely associated with halitosis.
- + Bad breath is not masked temporarily. It is treated and can be maintained.



BLIS FRESHBREATHKIT

BLIS FreshBreath™ Kit is clinically proven to promote and maintain fresh breath – not temporarily mask it. With a combination of BLIS K12™ lozenges, high-strength anti-bacterial mouthwash and a tongue cleaner, this easy to follow 4 week program will significantly improve breath odour for halitosis sufferers.

FreshBreath Kit contains:

- 1 x bottle of FreshBreath™ Lozenges (40) in peppermint flavor BLIS K12™
 - 1 x bottle of FreshBreath™ Mouthwash Concentrate 16ml
 - 1 x bottle of FreshBreath™ Mouthwash Activator 55ml
 - 1 x Tongue cleaner
 - 1 x Mixing container
 - 1 x Instruction leaflet
- FreshBreath maintenance lozenges (40) will be launched later in 2017

BLIS M18™

- + **Streptococcus salivarius** M18 (BLIS M18™) is a bacterial replacement probiotic specifically derived from the oral cavity and designed for use in the oral cavity.
- + BLIS M18 has been shown to be effective at killing **S. mutans**, a leading causative agent of tooth decay, during laboratory based trials. Bacteria responsible for the initiation of dental caries often produce lactic acid from dietary carbohydrate. This degrades the tooth enamel and dentine which can lead to cavities and eventual tooth loss.
- + BLIS M18 has been shown to produce the enzyme urease which can release ammonia in saliva helping to neutralize the acid produced by the cariogenic bacteria.



*Dental Caries
(Cavities)* >

*Gum Disease
(Gingivitis)* >



HOW DOES BLIS M18 WORK?

BLIS M18 works to stop plaque forming in the mouth by colonising the mouth with good bacteria that not only crowd out the bad bacteria, but help keep it under control through production of antimicrobial peptides. Plaque is where the bad bacteria can live and grow and if this is not kept under control, can be the cause of many dental issues.

Dental Caries (Cavities)

Bacteria accumulate (along with saliva, food particles and other natural substances) on the surface of the teeth in a sticky film called plaque. Plaque forms especially easily in cracks, pits or fissures in the back teeth; between teeth; around dental fillings or bridgework; and near the gum line. Some of the plaque bacteria convert sugar and starches in the foods we eat into acids. These acids dissolve minerals in the surface of the tooth, forming microscopic pits or erosions that get larger over time.

Tooth decay can occur when the tooth is exposed to plaque and acid. Caries can penetrate the protective enamel on the tooth down to the softer dentin – the main body of the tooth and continue through to the soft tooth pulp and the sensitive nerve fibres within it.

BLIS M18 helps to reduce dental plaque by keeping the bad bacteria under control. When dental plaque is not able to acidify, it cannot cause damage and tooth decay.



HOW DOES BLIS M18 WORK?

Gum Disease (Gingivitis)

People with gingivitis have inflamed gum tissue around their teeth, caused by bacteria found in dental plaque. Normal, healthy gums should be firmly attached to the teeth and underlying bone. They are pale pink in light-skinned people and brown, gray or mottled in people with darker complexions. If you have gingivitis, your gums are inflamed, red and swollen. They will bleed easily and may be tender. Mild gingivitis causes little pain and may be overlooked. If left unchecked, however, it can become severe. In some people, gingivitis progresses to periodontitis, which can lead to tooth loss.

Gingivitis is caused by plaque, a sticky film of bacteria that collects on your teeth, especially in crevices and spaces or around rough or broken fillings. The bacteria produce substances that can harm the gums. If plaque is not removed, it hardens into a deposit called calculus, commonly called tartar. Calculus irritates the gums and provides more surfaces for bacterial growth.

BLIS M18 colonises the mouth with good bacteria that supports healthy gums by not allowing the bad bacteria to colonise.



CLINICAL TRIALS

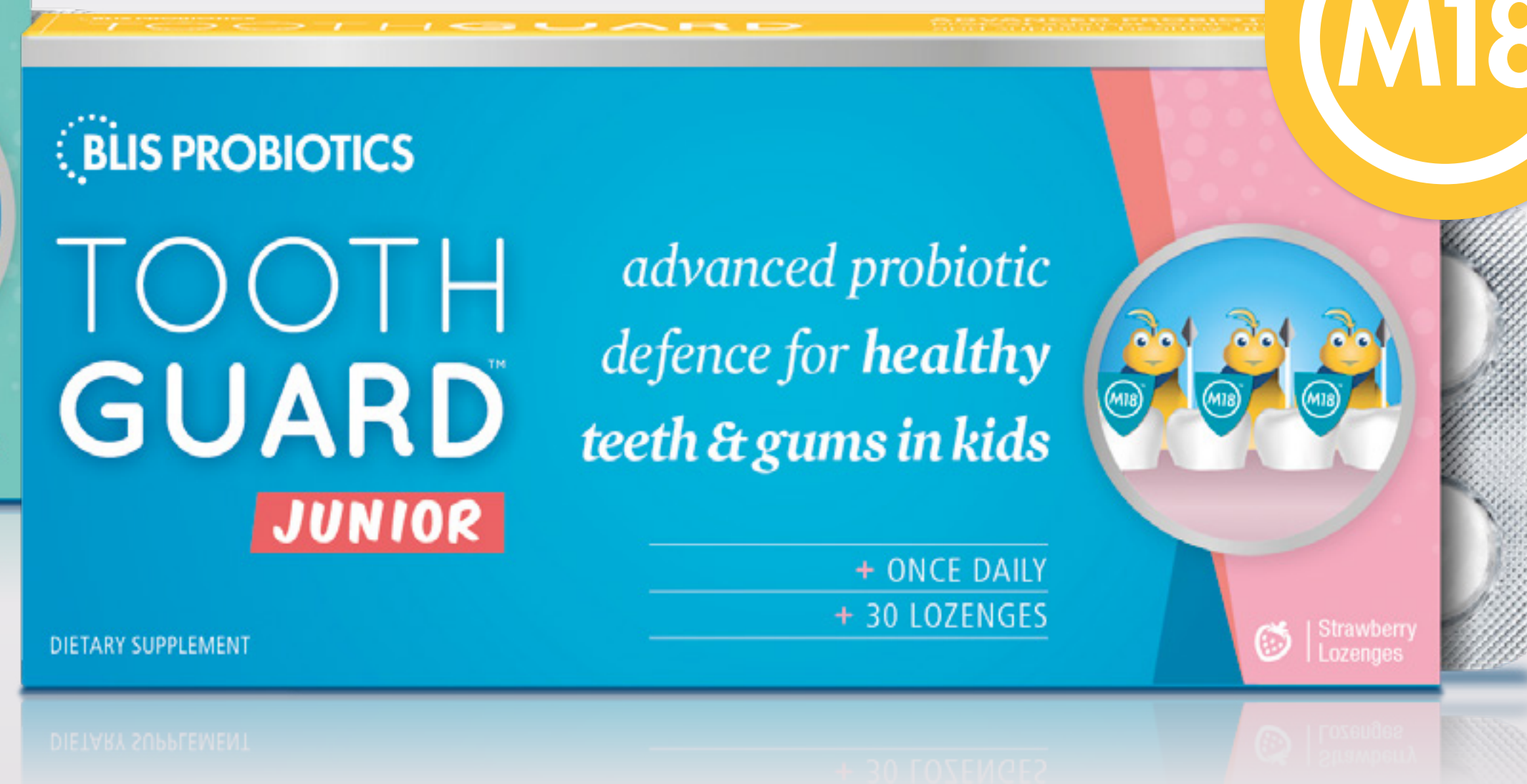
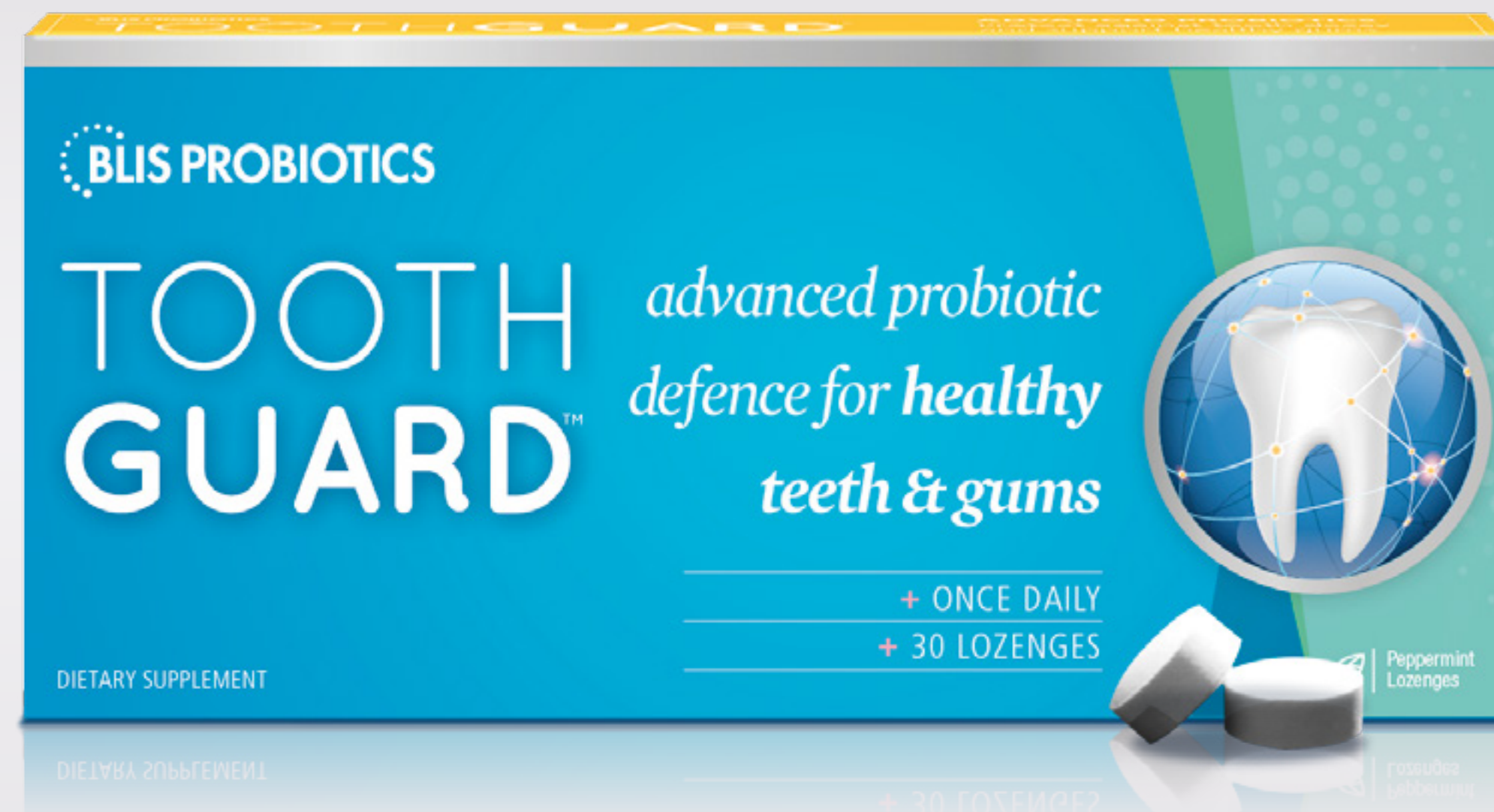
+ **3 trials:** 2 in children, 1 in adults

| | | |
|---|--|--|
| <i>Effect of Streptococcus salivarius on reduction of dental plaque</i> > | <i>Effect of Streptococcus salivarius M18 on dental caries</i> > | <i>Effect of Streptococcus salivarius M18 on periodontal disease</i> > |
|---|--|--|

+ Children who are at high risk of increased dental caries: significant reduction in plaque after 3 months resulting in a lower risk of more caries

+ Adults: reduction in plaque, reduction in gingivitis, periodontitis after 30 days

+ Considered very safe, no known drug-drug interactions or contra-indications



TOOTHGUARD

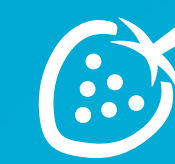
TOOTHGUARD JUNIOR



30 Peppermint flavoured probiotic lozenges



2.5bn cfu BLIS M18



30 Strawberry flavoured probiotic lozenges



2.5bn cfu BLIS M18

RRP \$24.95

CLINICAL TRIALS

Study name: Effect of *Streptococcus salivarius* M18 on reduction of dental plaque

Subjects: Total: 100 5-10 year olds with >3 dental restorations with one in the past year were recruited for this trial.

Active: 40 (12M,28F) **Placebo:** 43 (21M,22F)

Background: The probiotic *Streptococcus salivarius* strain M18 offers the potential to confer oral health benefits as it produces bacteriocins targeting the important cariogenic species *Streptococcus mutans*, as well as the enzymes dextranase and urease, which could help reduce dental plaque accumulation and acidification, respectively.

Summary: Commercial in confidence. In a randomized double-blind, placebo controlled study of 100 dental caries-active children, treatment with M18 was administered for 3 months and the participants were assessed for changes to their dental health. At treatment end, the plaque scores were significantly ($p \leq 0.05$) lower for children in the M18-treated group, especially in subjects having high initial plaque scores. Those children who colonised with BLIS M18 exhibited reduced *S. mutans* counts, indicating that the anti-caries activity of M18 probiotic treatments may be enhanced with efficient colonization.

No significant adverse events were reported.

Publication: Burton, J. P., B. K. Drummond, et al. (2013). "The influence of the probiotic *Streptococcus salivarius* M18 on indices of dental health in children: a randomised double-blind placebo-controlled trial." *J. Med. Microbiol.*

Comment: This was the first trial demonstrating the dental benefits of BLIS M18 in a double-blind placebo controlled trial. The outcomes and lack of adverse events were very encouraging.

CLINICAL TRIALS

Study name: Effect of *Streptococcus salivarius* M18 on dental caries

Subjects: 76 children (6-17 years) categorised as high risk for dental caries were recruited. 38 were in the treated group and 38 in the control (no lozenge) group.

Background: As a follow up to the initial clinical trial investigating BLIS M18 in dental caries, this Italian group employed the clinically proven caries-risk analysis algorithm known as the Cariogram. This assesses 9 key factors associated with dental caries and determines a “Risk score” of likely new development of caries. This trial recruited children who were deemed to be at risk and assessed their cariogram score before and after either a dosing regimen with one a day BLIS M18 lozenges for 90 days (active) or, with receiving no lozenges (control).

Outcome: Following 90 days the active group demonstrated a statistically significant 30% reduction, in the chance of developing caries compared to the control group.

Publication: Di Pierro et al. Cariogram outcome after 90 days of oral treatment with *Streptococcus salivarius* M18 in children at high risk for dental caries: results of a randomized, controlled study. *Clinical, Cosmetic and Investigational Dentistry* 2015;7 107–113.

Comment: Using an alternate clinically validated assessment technique this trial further endorses the benefit of daily delivery of *S. salivarius* M18 to help improve dental health.

CLINICAL TRIALS

Study name: Effect of *Streptococcus salivarius* M18 on periodontal disease

Subjects: 28 subjects who presented with clinically determined periodontal disease were recruited for this trial. The test group contained 14 subjects who received active *S. salivarius* M18 lozenges for 30 days, while the other 14 subjects did not receive any lozenges. The trial ran for 30 days with a follow up period at a further 30 days later. Commercial in confidence.

Background: *S. salivarius* strain M18 has been demonstrated to inhibit both dental and periodontal pathogens in the laboratory. This trial wanted to assess the efficacy of *S. salivarius*-containing probiotic lozenges, in the treatment of periodontal disease.

Outcome: 28 subjects with periodontal disease were recruited and split into two groups: 14 who were to receive *S. salivarius* M18 lozenges (test) and 14 who did not (control). Various clinical parameters (e.g. plaque index, gingival index, modified sulcular bleeding index and probing pocket depth) were recorded and assessed at baseline, day 15, 30, 45 and day 60.

The Test group showed significant improvement in all measured parameters when compared to that of the Control group. After stopping probiotic administration on day 30, the test group showed a significant increase in all the clinical parameters except probing pocket depth.

Publication: Scariya et al. Int J Pharm Bio Sci 2015 Jan; 6(1): (P) 242 - 250.

Comment: This is the first controlled trial assessing the efficacy of *S. salivarius* M18 lozenges on periodontal disease.