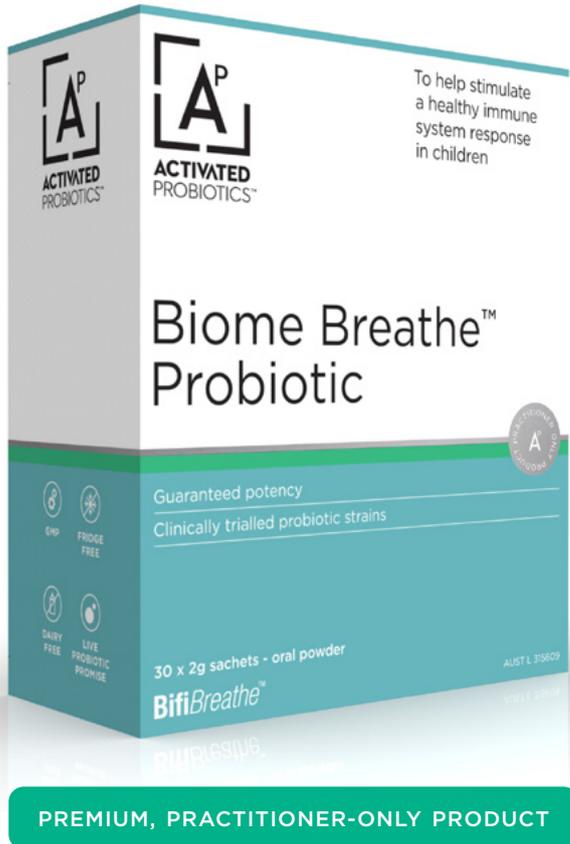




# Biome Breathe™ Probiotic

To help stimulate a healthy immune  
system response in children



30 x 2g sachets  
Unflavoured  
oral powder  
AUST L 315609

May support lung health via the gut-lung axis

Clinically trialled probiotic strains

Guaranteed potency

## INDICATION

- Biome Breathe™ helps stimulate a healthy immune system response in children

## FORMULATION

<i>Lactobacillus salivarius</i> LS01 (DSM 22775)	1 BLB*
<i>Bifidobacterium breve</i> B632 (DSM 24706)	1 BLB*
<b>Total live bacteria</b>	<b>2 BLB*</b>

\*BLB = Billion Live Bacteria

## DIRECTIONS FOR USE

**Children over 3 years:** Take one sachet daily, or as directed by a healthcare practitioner. Add to water or milk, or mix into yoghurt.

## NO ADDED

GMOs, wheat, gluten, dairy, lactose, fructose, yeast, nuts, seeds, peanut, soy, egg, fish, shellfish, or animal derivatives. No artificial colours, flavours, sweeteners, or preservatives.



GMP



LIVE  
PROBIOTIC  
PROMISE



DAIRY  
FREE



ONE A DAY  
FORMULATION



FRIDGE  
FREE

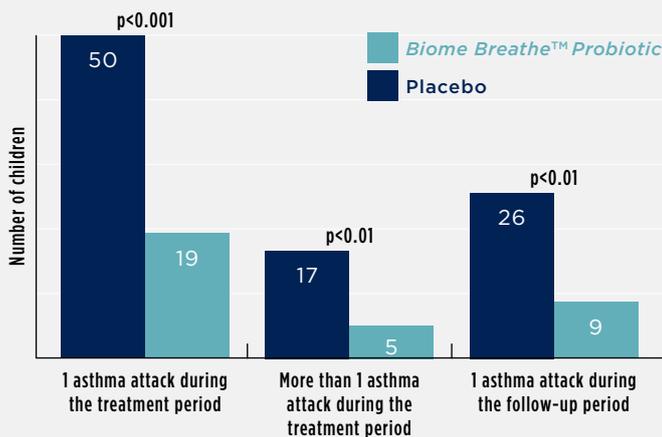


VEGAN

Activated Probiotics™ formulate premium probiotic products backed by cutting edge scientific research on the human gut microbiome. Using targeted bacterial strains at doses supported by clinical trials, we seek to provide tangible improvements in health and wellbeing with a new generation of evidence-based probiotics.



**FIGURE 1: Children Experience Significantly Fewer Asthma Attacks with *Biome Breathe™* Probiotic**



*Biome Breathe™* Probiotic clinical trial results (unpublished; received via personal communication). During the 4-month treatment period, significantly fewer children in the *Biome Breathe™* Probiotic group reported experiencing an asthma attack (n=19), compared to the children in the placebo group (n=50) (p<0.001). Further, significantly fewer children in the *Biome Breathe™* Probiotic group reported experiencing more than one asthma attack (n=5), compared to the children in the placebo group (n=17) (p<0.01). During the 4-month follow-up period, significantly fewer children in the *Biome Breathe™* Probiotic group reported experiencing an asthma attack (n=9), compared to the children in the placebo group (n=26) (p<0.01).

## GUT-LUNG AXIS

The gut microbiota is known to influence immune responses at distant sites, including the lungs<sup>1</sup>. The bidirectional communication between the gut and the lungs is described as the gut-lung axis<sup>2</sup>, and a growing body of research is uncovering an emerging role of the gut microbiota in respiratory diseases, including asthma<sup>3</sup>. For instance, both pre- and post-natal exposure to antibiotics - which disrupts the gut microbiome - is associated with an increased risk of developing asthma<sup>4</sup>.

## ASTHMA

Asthma is a common, chronic condition of the airways, characterised by episodes of wheezing, shortness of breath, coughing, and chest tightness due to narrowing of the airways. The severity of the condition ranges from mild, intermittent symptoms, through to severe and persistent wheezing and shortness of breath. A number of factors can trigger asthma, such as exposure to allergens, environmental

irritants, exercise, and viral respiratory infections. The inflammatory cascade seen in mild to moderate allergic asthma is mediated by T helper type 2 (Th2) cells, which release the pro-inflammatory cytokines IL-4, IL-5 and IL-14<sup>5</sup>. The most commonly used therapeutic agents for the management of mild to moderate asthma included inhaled glucocorticoids and bronchodilators<sup>5</sup>.

## THE BURDEN OF ASTHMA IN AUSTRALIA

Australia has one of the highest rates of asthma of any developed nation in the world. An estimated 11% of the Australian population suffer from asthma, based on self-reported data from the 2017-18 National Health Survey<sup>6</sup>. Among children, asthma is the leading cause of non-fatal burden of disease in boys aged 5-14, with 15% of children in this age group affected, and the second leading cause of non-fatal burden of disease in girls aged 5-14, with 12% of girls in this age group affected<sup>7</sup>.

## CLINICAL EVIDENCE

A number of preclinical studies have demonstrated that probiotics have anti-inflammatory properties and anti-allergic effects in animal models of asthma<sup>8, 9, 10, 11</sup>. For example, several studies conducted in mouse models have shown that regulatory T cells (Tregs), which downregulate the allergic response in asthma, can be induced by strains of *Lactobacilli* and *Bifidobacteria*<sup>12</sup>. To investigate whether specific strains of probiotic bacteria might have beneficial effects on humans with asthma, Drago *et al* isolated peripheral blood mononuclear cells (PBMCs) from patients with allergic asthma, and incubated them with two probiotic strains (*Lactobacillus salivarius* and *Bifidobacterium breve*) alone and in combination<sup>13</sup>. The experiment showed a statistically significant increase in IL-10 secretion from PBMCs under all three conditions<sup>13</sup>. IL-10 is an anti-inflammatory cytokine, and is a powerful inhibitor of pro-inflammatory cytokines, including IL-4 and IL-5.

On the basis of these encouraging preclinical results, a randomised, double-blind, placebo-controlled trial was recently completed in Italy, which sought to investigate whether supplementation with these two probiotic strains could reduce symptomatic episodes in children aged 2-14 years diagnosed with asthma or recurrent wheezing. The trial participants (n=422) were randomised into two groups: a probiotic group (n=212), who received a sachet of *Biome Breathe™* Probiotic twice daily for 2 months, followed by one sachet once daily for a further 2 months; or a placebo group (n=210), who received sachets containing maltodextrin only. During the treatment and follow-up periods, the number of asthma crises and episodes of wheezing were recorded by the child's paediatrician. The study found that significantly fewer children experienced acute exacerbations of their asthma ('asthma attacks') during both the treatment and follow-up periods (Figure 1). These results are consistent with a recent systematic review and meta-analysis of probiotic supplementation in children with asthma which found that the number of children with fewer episodes of asthma was significantly higher in the probiotics group, when compared with the control group (RR 1.3; 95% CI 1.06-1.59)<sup>14</sup>.

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