



PrecisionBiotics™

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every strain

Clinical evidence summary

Paediatric Gut Health &
the 35624™ Probiotic Strain

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Note disclaimer on last page.

Paediatric Gut Health & the 35624™ Probiotic Strain

The pathophysiology of irritable bowel syndrome (IBS) is not fully understood¹. However, in both adults and children, alterations in the composition of the gut microbiome may play a role in the development of Disorders of Gut-Brain interactions (DGBIs), an umbrella term which includes IBS^{2-7,19}.

The influence of the gut microbiome on gut health and function has prompted research into the potential of probiotics for IBS^{8,9}. This has resulted in international clinical guidelines recommending the use of specific probiotic strains for managing symptoms of IBS^{8,10}. Clinical and real-world data in adults and children show the *Bifidobacterium longum* 35624™ probiotic strain may be effective in managing the global symptoms of IBS and may also improve the impact of IBS symptoms on quality of life¹¹⁻¹⁸.

Definitions:

Microbiota:

All microscopic organisms (e.g. bacteria, archaea, viruses, fungi, some eukaryotes) living in a defined habitat or environment (such as the human gut).

Microbiome:

All microorganisms living in a defined habitat (the microbiota), including:

- Their internal molecules (e.g. nucleic acids, proteins, lipids, polysaccharides, etc)
- The metabolites they produce (e.g. short chain fatty acids, toxins, etc)
- Their surrounding host environment (e.g. the cells and nutrients in the human gut)

While the microbiome contains microbiota, the microbiome is more than just microbiota alone.

Note: The 35624™ strain, formerly classified as *Bifidobacterium infantis*, has been reclassified as belonging to the species *Bifidobacterium longum*.



Key Points:

- IBS is a common paediatric DGBI, affecting approximately 3% of children and adolescents worldwide.¹⁹
- Gut bacteria profiles of children with IBS may differ from those without⁵⁻⁷
- Low-grade inflammation may be a component of IBS in some paediatric cases²⁰⁻²²
- Probiotics have been recognised in the management of IBS in children^{10, 21, 23, 24}
- The *Bifidobacterium longum* 35624™ strain has demonstrated systemic immunomodulatory properties²⁵
- In adults, clinical and real-world data has shown *Bifidobacterium longum* 35624™ to be associated with improvements in the management of IBS symptoms and quality of life, reduction in the severity of IBS¹²⁻¹⁸ and modulation of inflammatory biomarkers¹³
- In children, a real-world, open-label clinical study found that *Bifidobacterium longum* 35624™ can help reduce the severity of IBS symptoms, and reduce the impact of IBS symptoms on life¹¹
- The 35624™ strain has been carefully selected for its safety and efficacy by PrecisionBiotics®, who have over 25 years' experience of scientific research and expertise in this field



The Gut Microbiome in Children

The composition of the gut microbiome, which is established early in life, is influenced by various factors such as mode of delivery at birth, breastfeeding, geographic location, household exposures (e.g. to pets) and nutrition²⁶. In the first two years of life, the gut microbiome develops and changes, usually stabilising by the age of three years²⁶. A rich diversity of microbial species in the gut is considered healthy^{27,28}.

Whilst it is difficult to modify the composition of the gut microbiome beyond early life^{26,29}, aging, illness, use of medications such as antibiotics, lifestyle and diet may all have an effect^{30,31}. Long-term and consistent dietary changes, such as eating a diet rich in fruits, vegetables and wholegrains, may have a positive effect on the composition of the gut microbiome³². Additionally, supplementation of the gut microbiome with certain probiotics to confer potential health benefits has been recognised in children^{23,24}.

The Gut Microbiome in Health and Illness

The gut microbiome plays a key role in the regulation of human health³³. It is involved in many functions in the body including³³:



- Maintenance of normal gut physiology and health, through regulation of epithelial cell proliferation and differentiation
- Protection against pathogens, through colonisation of mucosal surfaces and production of antimicrobial substances
- Regulation of multiple systems and processes including the immune system, digestion, metabolism, insulin sensitivity and secretion
- Modulation of gut-brain communication, in turn affecting mental and neurological functions

An altered gut microbiome has been associated with numerous health conditions³¹. Whilst it is not fully understood whether this is a cause or consequence, there is speculation that alteration of the gut microbiome may be related to a variety of diseases, including metabolic, immunological, cardiovascular and neuropsychiatric conditions, as well as gastrointestinal (GI) conditions, such as IBS³³.



IBS in Children

IBS is a relapsing and long-term condition that affects the digestive system³⁴. A diagnosis of IBS is made based on patient-reported symptoms, in the absence of other detectable diseases^{9,35}. In the paediatric population, Rome V classifies IBS as a Disorder of Gut–Brain Interaction (DGBI), within the broader group of paediatric DGBIs, replacing the former terminology of functional gastrointestinal disorders (FGIDs)⁹.

‘The Rome V guidelines state that the diagnostic criteria* must include all of the following¹⁹:

- Intermittent abdominal pain at least 4 days per month that is either related to defecation and/or change in stool frequency and/or a change in stool form
- Abdominal pain is the predominant symptom in children with constipation or diarrhoea
- Pain should not be exclusively associated with menstrual period
- After appropriate evaluation, symptoms cannot be explained by other conditions

*Criteria fulfilled for at least 2 months before diagnosis

IBS affects individuals across the lifespan, including children and adolescents, with paediatric prevalence estimated at 3%¹⁹. DGBIs are frequently encountered in healthcare settings and are associated with a significant impact on children and adolescents, including reduced quality of life, low mood, anxiety, school absenteeism, and missed work for caregivers^{20,36}.

Both the psychosocial factors and gastrointestinal symptoms associated with DGBIs can persist into adulthood³⁶.

The aetiology and pathophysiology of IBS in children

The aetiology and pathophysiology of IBS in children (and adults) are not completely understood, however, different mechanisms have been suggested regarding the development of IBS³⁷. Some potential predisposing factors occur outside of the gut, for example, genetic predisposition, environmental influences and psychosocial disturbances^{1,22}. Diet is often attributed as a contributory factor for IBS, however, the exact relationship between diet and IBS has not been determined²². In addition, there may be a relationship between early life conditions (such as umbilical hernia, pyloric stenosis and cow's milk protein allergy) and IBS, although further studies are needed to confirm this²².

Some of the potential pathophysiological changes occurring in paediatric IBS within the gut are outlined below.

Inflammation and infection



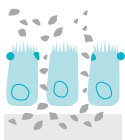
- Studies of children with IBS have shown an accumulation of inflammatory cells in the intestinal mucosa²²
- There may be an infectious trigger for IBS in some paediatric cases^{20,37}
- Increased incidence of IBS has been reported after an episode of bacterial gastroenteritis in children (post-infectious IBS)^{22,38}

Visceral hypersensitivity



- Visceral hypersensitivity (i.e. the increased perception of stimulus to the intestine, manifesting as pain or discomfort), is believed to have a key role in the pathogenesis of IBS³⁹
- Visceral hypersensitivity has been documented in paediatric populations with IBS⁴⁰
- Chronic inflammation of the intestinal mucosa combined with stress factors can cause visceral hypersensitivity in the lower GI tract³⁹

Increased intestinal permeability



- The gut-brain axis, gut microbiota and the intestinal barrier work together to provide nutrients and are involved in the development of the immune system³⁶
- A dysregulation of this system may lead to increased intestinal permeability and GI transit time, which can, in turn, cause symptoms such as abdominal pain and bloating³⁶
- There is some evidence that children with functional abdominal pain/ IBS have increased permeability in the proximal GI tract and colon⁴¹

Alterations in gut microbiome composition



- Studies in paediatric populations have found differences between the gut microbiome of those with IBS and those without^{5,7}
- Processes that are known to cause alterations in the gut microbiome may be associated with an increased risk of developing IBS, such as courses of antibiotics⁴² or small intestinal bacterial overgrowth⁴³

Clinical Guidelines for Probiotics in Paediatric IBS

- The European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN) Special Interest Group on Gut Microbiota and Modifications and the World Gastroenterology Organisation (WGO) Global Guideline on probiotics both recognise the benefit of using certain specific strains of probiotics in children with IBS^{10, 23}
- An Italian guideline for the management of IBS in children has given conditional recommendations for certain probiotics to treat global IBS symptoms²¹
- An expert consensus recommended certain probiotics for improving the symptoms of IBS in children²⁴
- A systematic review of the use of probiotics in functional abdominal pain disorders (incorporating IBS) concluded that probiotics may provide better pain relief (compared to placebo) for children with functional abdominal pain⁴⁴

Mechanism of Action of the 35624™ strain

The immunomodulatory properties of the *Bifidobacterium longum* 35624™ strain have been demonstrated in three double-blind, randomised, placebo-controlled trials in people with ulcerative colitis, chronic fatigue syndrome and psoriasis²⁵. These studies demonstrated that the 35624™ strain significantly reduced C-reactive protein and the proinflammatory cytokines TNF- α and IL-6, suggesting a systemic immunoregulatory mechanism of action²⁵.

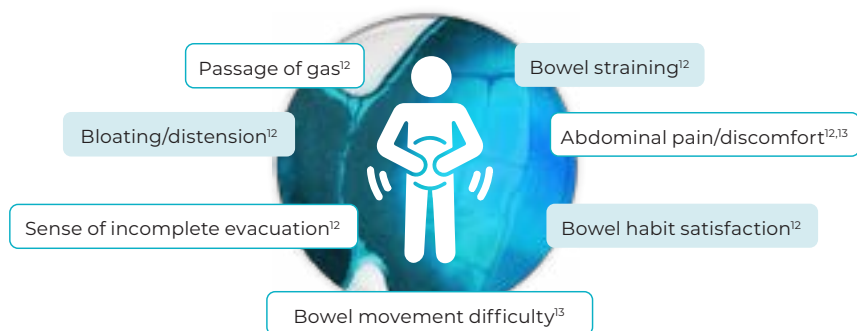
- Downregulating proinflammatory cytokines (e.g. IL-12 and TNF- α)
- Upregulating anti-inflammatory cytokines (e.g. IL-10, TGF- β)
- Activating regulatory T-cells

Additionally, results from pre-clinical models suggest that the unique exopolysaccharide (EPS) coating of the 35624™ strain mediates some of its immunoregulatory properties, playing a key role in the inhibition of proinflammatory cytokines (e.g. IL-17)^{48, 49}. This multifaceted mode of action is thought to prevent symptoms and tissue damage caused by chronic low-grade inflammation⁴⁵.

Clinical and Real-World Evidence for the 35624™ strain in IBS

Clinical trials in adults^{12, 13} and children^{11, 50} have demonstrated that *Bifidobacterium longum* 35624™ is a safe and well tolerated probiotic strain.

Randomised, placebo-controlled trials have demonstrated benefits in adults with IBS following supplementation with the 35624™ strain, including significant improvements ($p < 0.05$ vs placebo) in overall IBS symptom scores^{12, 13} and in certain inflammatory biomarkers¹³. In addition, there were significant improvements ($p < 0.05$ vs placebo) in specific symptoms of IBS, including:



Real-world, open-label studies of *Bifidobacterium longum* 35624™ have shown similar positive effects on GI symptoms, as well as improvements to quality of life^{14-17,*}

More recently, an open-label, single-arm clinical study demonstrated positive effects of 12 weeks of supplementation with the 35624™ strain in children and adolescents with IBS, including¹¹:

- Significant decreases in composite IBS severity scoring system (IBS-SSS) scores ($p < 0.0001$ vs baseline)
- 96.6% of participants experienced a clinically meaningful** improvement in their composite IBS-SSS score
- Significant improvements in all IBS-SSS domains ($p < 0.0001$ vs baseline; Figure 1)
- Numerical improvements in at least three IBS-SSS domains experienced by 98.3% of participants

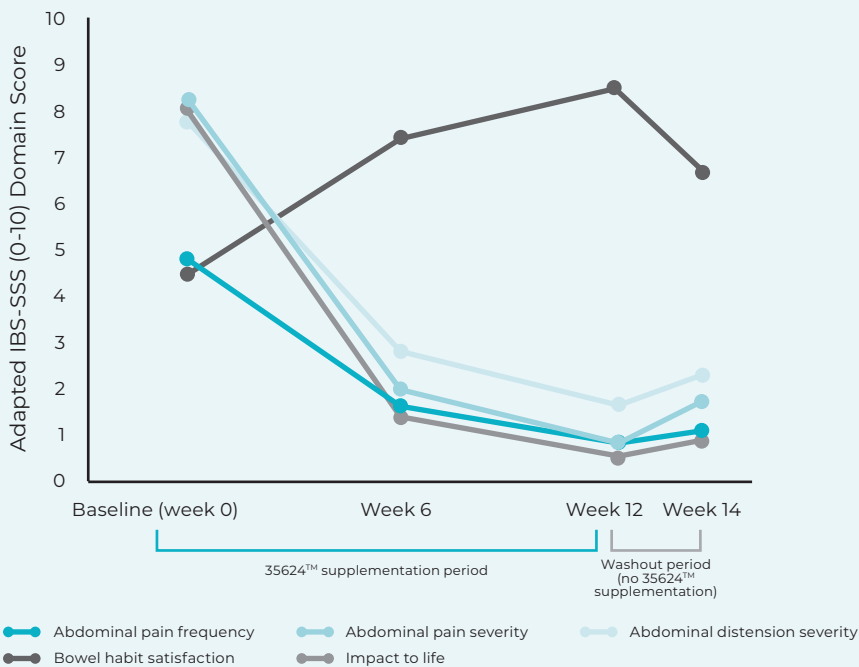


Figure 1: IBS-SSS domain scores during 35624™ supplementation period

*Please refer to Clinical Evidence Summary: Gut Health & the 35624™ Probiotic Strain for further details of the studies conducted in adults.

**≥50-point decrease in IBS-SSS score

- Improvements in the distribution of IBS severity categories, with decreases in the number of participants with severe or moderate symptoms, and increases in those either mild symptoms or in remission (Figure 2)

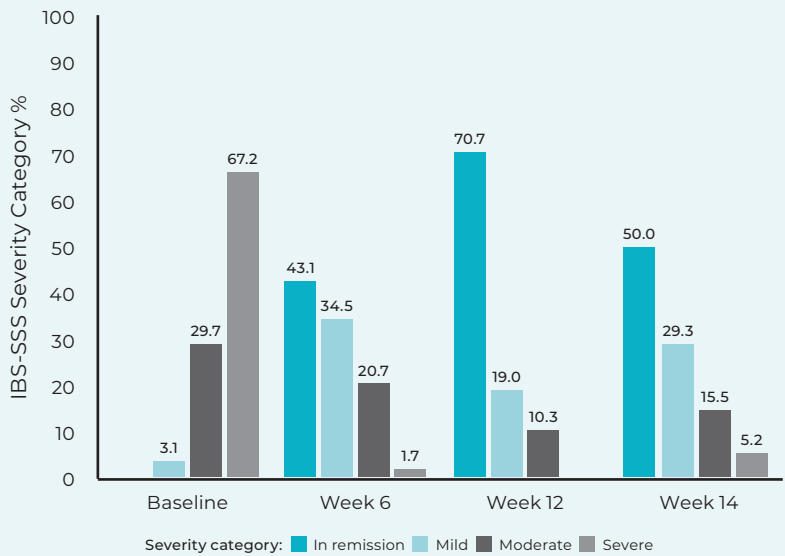


Figure 2: Percentage of participants in each IBS-SSS severity category by time-point

A further open-label study has shown intervention with the 35624™ strain may provide parallel improvements^{51,52}. At week 8, decreases in frequency and severity (Figure 3) were observed for all gastrointestinal symptoms, compared to baseline (all $p<0.001$).

Additionally, parents/children reported:

- Significant reduction in school absence ($p<0.001$) (Figure 4)
- Significant reduction in missed work days for parents ($p<0.001$)
- Significant reduction in the impact of symptoms on mood and family life ($p<0.001$)
- Significant increase in overall wellbeing ($p<0.001$)
- Overall, 70.0% of children were probiotic responders.

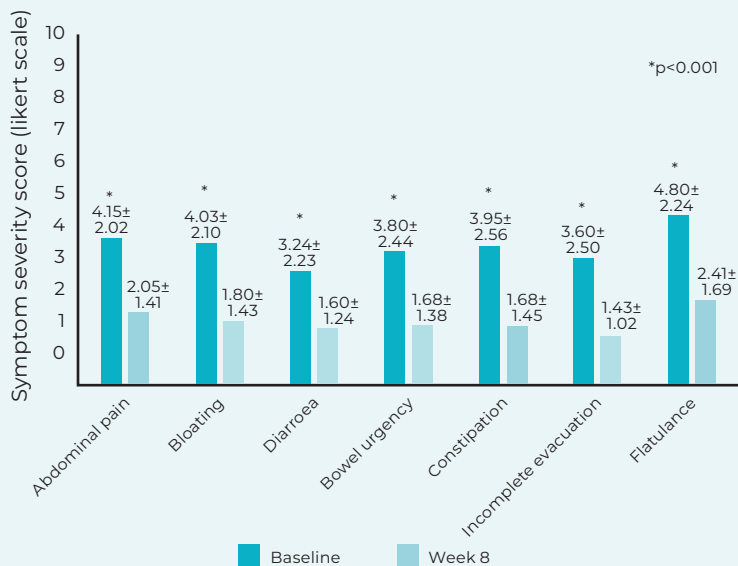


Figure 3: Symptoms severity score (likert scale) at week 8 ⁵²

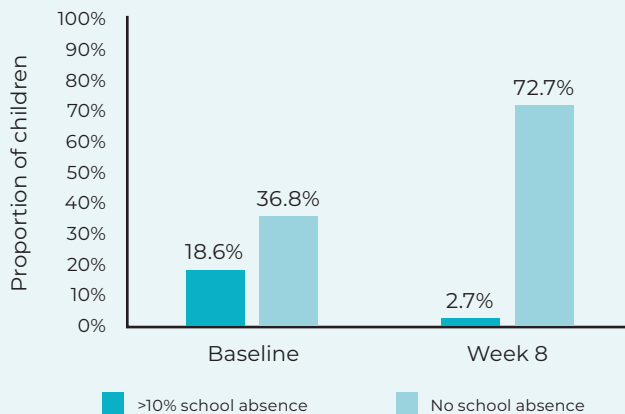


Figure 4: Proportion of Children missing school.⁵¹

Overview of Research Methods

Effects of *Bifidobacterium longum* 35624™ in children and adolescents with irritable bowel syndrome (Cruchet Muñoz et al, 2024)¹¹

A real-world, open-label, single-arm study, conducted in 64 children and adolescents (8-18y) with IBS as per the Rome IV criteria, with or without another FGID. Participants received 1x10⁹ colony-forming units of *Bifidobacterium longum* 35624™ daily for 12 weeks. The IBS symptoms of the participants were measured by the study physician at baseline (one week before intervention period), week 6 and 12 of the intervention period and week 14 (washout period with no supplementation for two weeks after the intervention period). An adapted IBS-SSS measured five domains (abdominal pain frequency [number of days with pain]; abdominal pain severity; abdominal distension severity; bowel habit satisfaction; and impact to life). The Wong-Baker FACES® and numeric pain rating scales were used to obtain children's responses. Diaries were also provided to participants, to record parent and child perspectives of the number of IBS symptoms present via the adapted Questionnaire on Paediatric Gastrointestinal Symptoms (QPGS) and stool consistency via the Bristol Stool Form Scale during the intervention period.

Effects of *Bifidobacterium longum* 35624™ in children and adolescents with gastrointestinal symptoms (Sorensen et al, 2025)^{51,52}

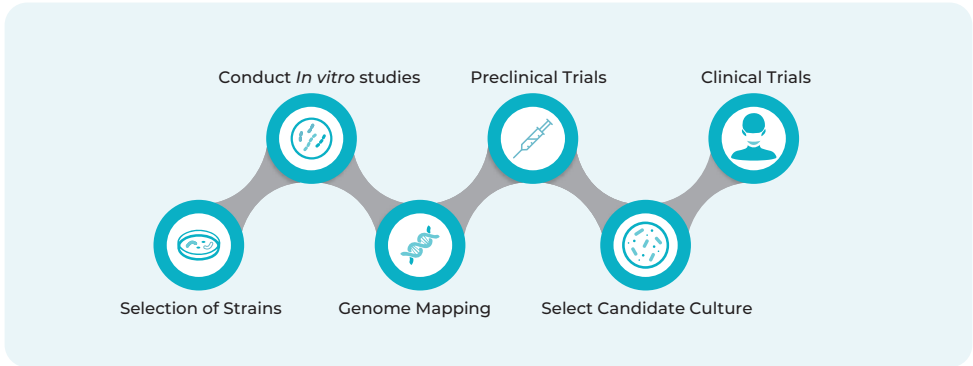
A real-world, open-label, single-arm, prospective study enrolled 220 children (3-12y) of whom 100% had regular tummy pain and 84.5% had tummy pain associated with changes in bowel habit, common in IBS. Participants received 1x10⁸ colony-forming units of *Bifidobacterium longum* 35624™ daily for 8 weeks. Symptoms were assessed at baseline and following the 8 week intervention period through an online questionnaire. The questionnaire was used to assess the frequency and severity of GI symptoms, absence, impact to life wellbeing and acceptability. A probiotic response was defined as a ≥30% reduction in abdominal pain severity at Week 8 compared with baseline. Changes from baseline to Week 8 were analysed using paired samples t-tests and McNemar's tests, with statistical significance set at p<0.05. In addition, correlations between gastrointestinal symptoms and quality of life were explored.

In Conclusion

Alterations in the gut microbiome composition may occur in children with symptoms of IBS compared to those without⁵⁻⁷. Clinical guidelines recognise the potential role of probiotics in the management of the symptoms of IBS in children^{10, 21, 23}. Results from clinical studies and real-world evidence have previously demonstrated that supplementation with the 35624™ strain helps to significantly improve GI symptom severity and bowel habits in adults with IBS¹²⁻¹⁸. More recently, the 35624™ strain has been shown to significantly improve IBS symptoms including abdominal pain, abdominal distension, bowel habit satisfaction and impact to life, in children and adolescents with IBS¹¹ and significantly reduce frequency and severity for all gastrointestinal symptoms in children, while Additionally, parents/children reported fewer missed days of school, work, and higher wellbeing scores.^{51,52}

The Precise Approach to Probiotic Development

For over twenty years, PrecisionBiotics has discovered and developed unique probiotic strains in partnership with scientists and clinical experts from a world-leading centre of research into the microbiome and gut-brain axis - the APC Microbiome Institute, University College Cork, Ireland. This follows a robust process to develop targeted probiotics:



The result has been the development of safe, effective, evidence-based probiotic supplements with strains selected for their specific action for specific conditions.



Learn how *Bifidobacterium longum* 35624™ may help in the management of IBS symptoms in adults and children by visiting our CPD Learning Hub:

www.precisionbiotics.science

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