

BioGaia Protectis® Baby Drops

# Providing Colic Relief Worldwide

Sold in over  
100 Countries

**BioGaia®**  
Supporting your invisible heroes

Intended for Health Care Professionals



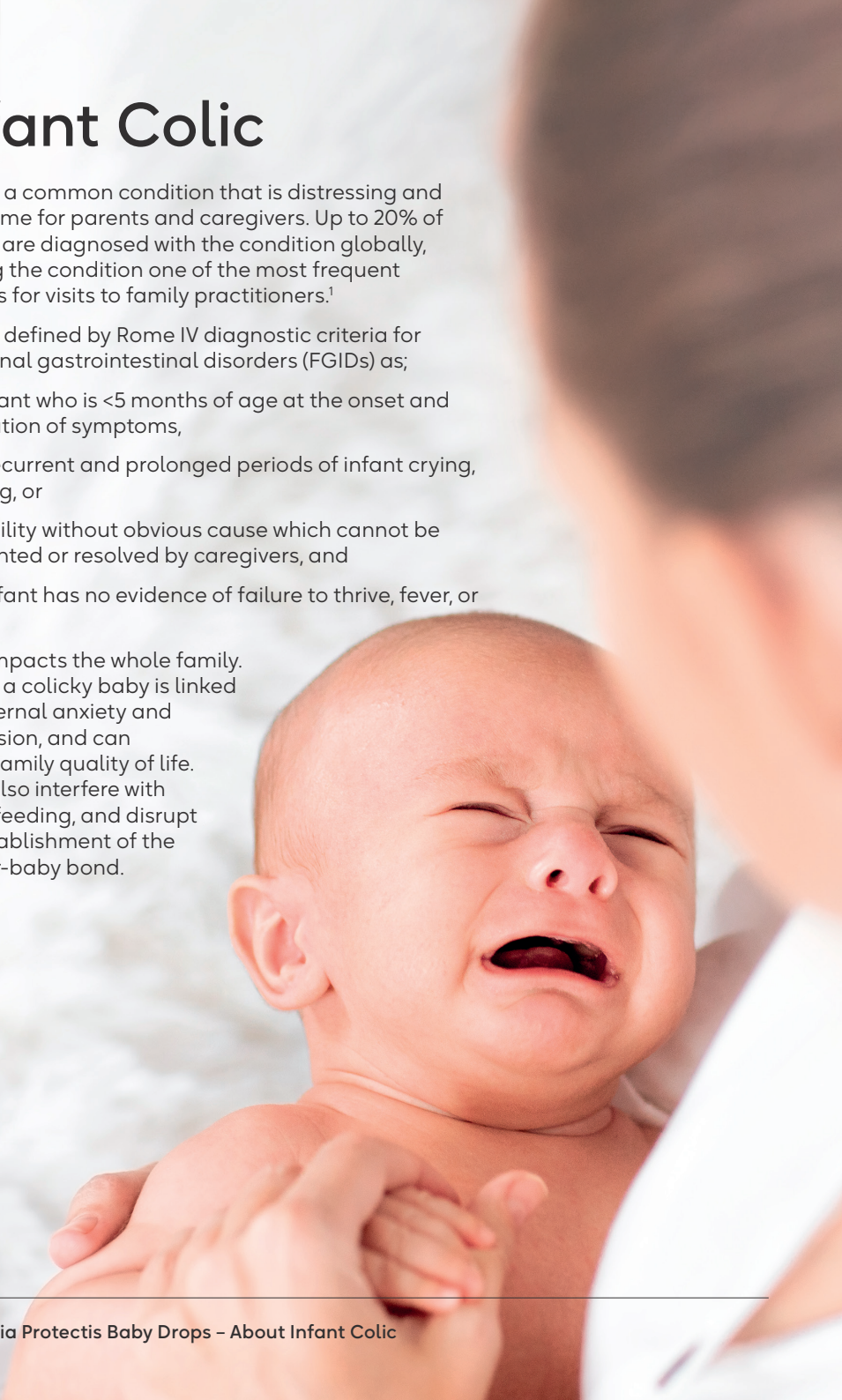
# Infant Colic

Colic is a common condition that is distressing and worrisome for parents and caregivers. Up to 20% of infants are diagnosed with the condition globally, making the condition one of the most frequent reasons for visits to family practitioners.<sup>1</sup>

Colic is defined by Rome IV diagnostic criteria for functional gastrointestinal disorders (FGIDs) as;

- an infant who is <5 months of age at the onset and resolution of symptoms,
- has recurrent and prolonged periods of infant crying, fussing, or
- irritability without obvious cause which cannot be prevented or resolved by caregivers, and
- the infant has no evidence of failure to thrive, fever, or illness.<sup>1</sup>

Colic impacts the whole family. Having a colicky baby is linked to maternal anxiety and depression, and can affect family quality of life. It can also interfere with breastfeeding, and disrupt the establishment of the mother-baby bond.



# The Microbiota and Probiotics

The gastrointestinal microbiota is thought to play an important role in the etiology of colic.<sup>2</sup> Studies have shown that newborns, who later develop infant colic, have a lower relative abundance of *Lactobacillus* in the first stool compared to those who remain healthy.<sup>3</sup> Additionally, low levels of *Lactobacillus* and *Bifidobacterium* and high levels of *E. coli* have been observed in colicky infants compared to non-colicky infants.<sup>4</sup>

Numerous studies have shown that colic may be alleviated, and excessive crying reduced by supplementation with specific probiotics, primarily *L. reuteri* Protectis® (*Limosilactobacillus reuteri* DSM 17938). *L. reuteri* Protectis is the most studied probiotic for the management of infant colic.<sup>5</sup>

**"Live microorganisms that, when administered in adequate amounts, confer a health benefit on the host"**<sup>6</sup>

Definition of probiotics

# BioGaia Protectis<sup>®</sup> Baby Drops is Special

- The most researched probiotic in infant colic<sup>5</sup>
- Reduces crying and fussing in colicky babies
- Improves the well-being of the mother
- Improves family quality of life



BioGaia Protectis baby drops is a probiotic supplement with multifunctional benefits that promotes a healthy functioning gastrointestinal system, helping restore the balance of a baby's digestive system. As a result, reduces crying and fussing in colicky babies.





# How BioGaia Protectis® Baby Drops Helps the Crying Baby

Colic is a multifactorial condition, which is not fully understood. The latest scientific hypothesis for its pathogenesis explains how an immature gut may affect a colicky baby, resulting in excessive and inconsolable crying.

## Proposed Pathogenesis for Colic

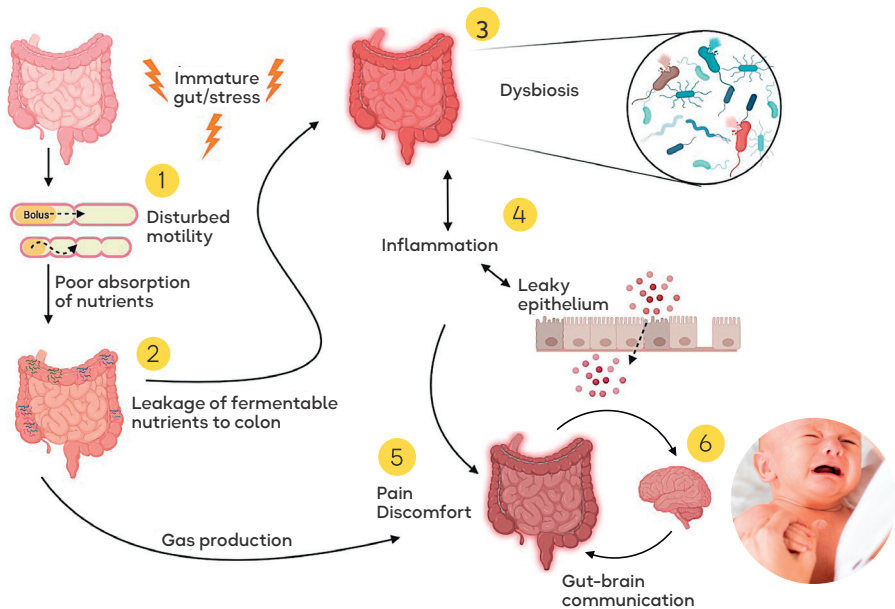


Fig 1. Immaturity of the gastrointestinal tract can lead to disturbed intestinal motility. The motility (1) results in poor absorption of nutrients and leakage of fermentable nutrients (2), giving rise to both increased gas production and dysbiosis (3). The dysbiosis triggers inflammation (4) noticed by a leaky gut epithelium. The inflammation, leaky epithelium and gas production are all believed to trigger pain and discomfort (visceral pain) (5) through the gut-brain axis, resulting in excessive inconsolable crying (6).

# Mode of Action of the Strain *L. reuteri* Protectis®

BioGaia Protectis baby drops contains the well documented probiotic strain *L. reuteri* Protectis, a multifunctional strain having different effects in the gastrointestinal tract.

*L. reuteri* Protectis positively affects the immature gut by slowing down the propagation in the small intestine, enabling proper digestion and absorption of nutrients. It also decreases the leakage of fermentable carbohydrates to the colon. In the colon, *L. reuteri* Protectis increases intestinal motility, which speeds up transportation of the remaining contents resulting in reduced gas formation and reduced dysbiosis.<sup>7</sup> The improved microbial balance<sup>8</sup> subsequently leads to a reduction in inflammation<sup>9</sup> and a reduced leakage by epithelial cells.<sup>10, 11</sup>

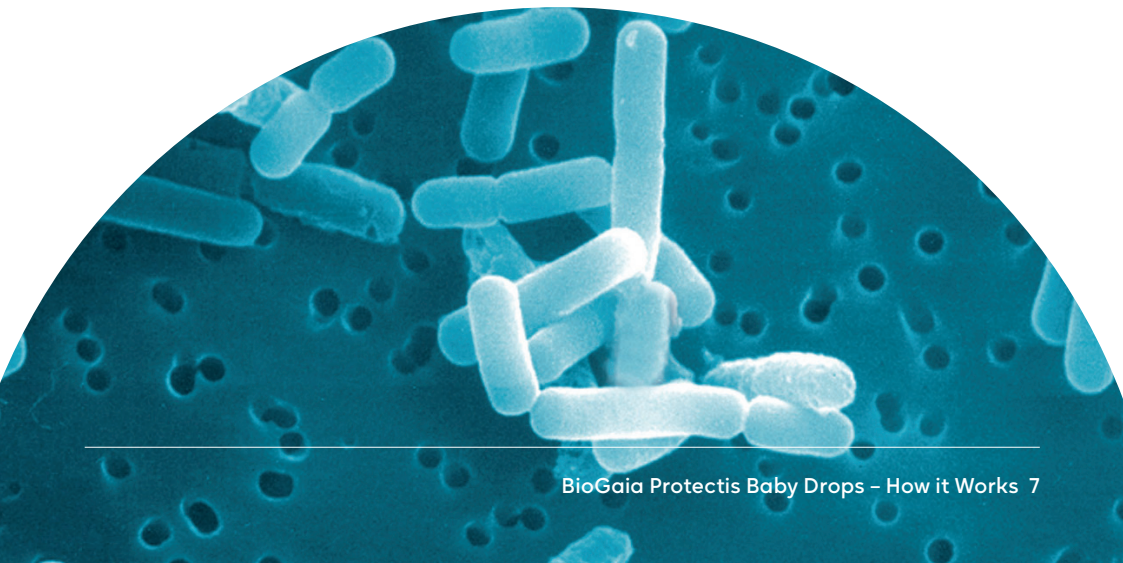
Finally, *L. reuteri* Protectis blocks the pain receptor TRPV-1 leading to reduced nerve firing and reduced pain.<sup>12</sup> Together, these effects may explain the reduced crying in colicky babies.

## Colic is a **Multifactorial Condition** Linked to:

- Disturbed gut motility
- Dysbiosis in microbiota composition
- Low-grade intestinal inflammation
- Visceral hypersensitivity

## *L. reuteri* Protectis is a **Multifunctional Probiotic** Shown to:

- Positively affecting gut motility
- Reduce dysbiosis
- Have anti-inflammatory effects
- Reduce visceral pain



# BioGaia Protectis®

## Baby Drops – Effective and Safe

BioGaia Protectis baby drops with *L. reuteri* Protectis is the most researched probiotic in infant colic.<sup>5</sup> *L. reuteri* Protectis is an indigenous probiotic whose natural habitat is human babies. Passed down from generation to generation during childbirth and breastfeeding, *L. reuteri* has co-evolved with humans since the beginning of time. In fact, humans have a symbiotic relationship with *L. reuteri* that is significant to our health.<sup>13</sup>

Our trusted, multi-award-winning drops have been proven to reduce crying and fussing in colicky babies. As a result, our drops also have a positive effect on the family quality of life.

Eight colic treatment studies and two colic prevention studies have shown a significant reduction in daily inconsolable crying time for babies supplemented with BioGaia Protectis baby drops.

8

### Colic Treatment Studies<sup>14-21</sup>

*L. reuteri* Protectis:

- Significantly reduced daily inconsolable crying time
- Improved the well-being of mom and baby
- Improved family QoL

2

### Colic Prevention Studies<sup>22, 23</sup>

*L. reuteri* Protectis:

- Significantly reduced daily inconsolable crying time
- Reduced formula use
- Improved breastfeeding rates
- Saved families money

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### Meta-analyses<sup>24-35, 42-44</sup>

*L. reuteri* Protectis:

- Effective in infant colic, especially in exclusively or predominantly breastfed infants

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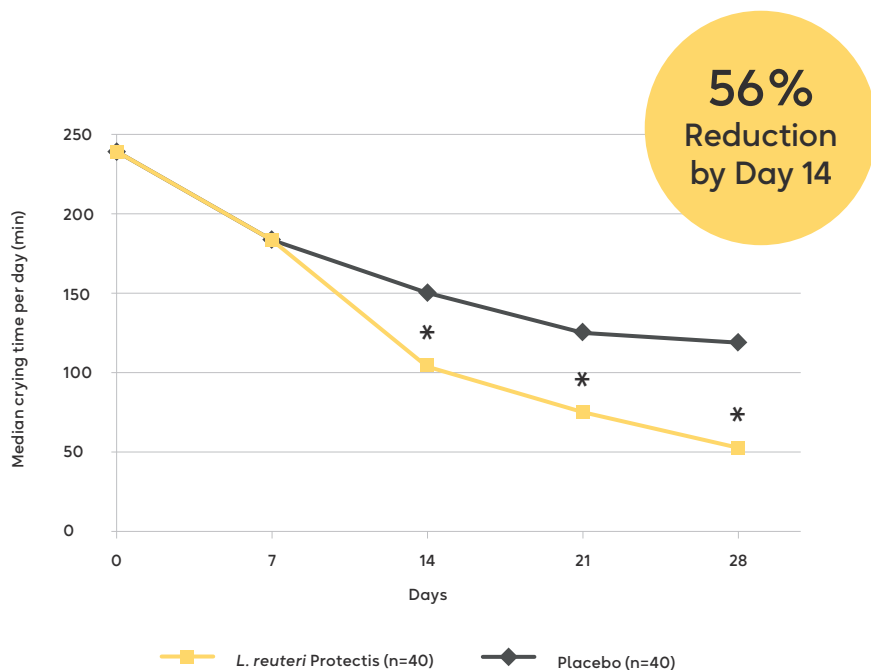
### International Clinical Guidelines<sup>5, 36-40</sup>

- Supports the use of *L. reuteri* Protectis for management of infant colic in breastfed infants



# Significant Reduction of Crying Time

In a randomised, double-blind, placebo controlled study *L. reuteri* Protectis was shown to significantly reduce crying time by day 14, in breastfed infants with colic.<sup>14</sup>



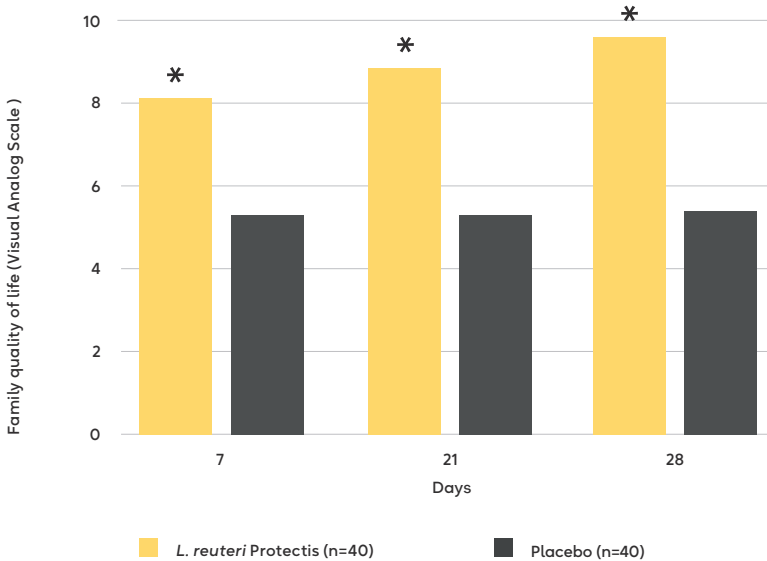
\*Statistically significant difference ( $p < 0.0001$ ) compared to placebo.

## Study Facts

- Double-blind, placebo-controlled, study in 80 exclusively or predominately breastfed colicky infants
- Five drops per day of *L. reuteri* Protectis (n=40) or placebo (n=40) for 21 days
- Primary outcomes
  - Reduction in daily average crying time of  $\geq 50\%$
  - Crying time in minutes/day at 7, 14, 21 and 28 days
- Secondary outcomes
  - Reduction in daily crying time to less than three hours per day
  - Persistence of colic after intervention
  - Parental perception of colic severity
  - Parental and family quality of life

# Improved Family Quality of Life

In the randomised, double-blind, placebo controlled study by Szajewska H. et al 2013 showing a reduction in crying time, *L. reuteri* Protectis was also shown to significantly improve family quality of life throughout the study.



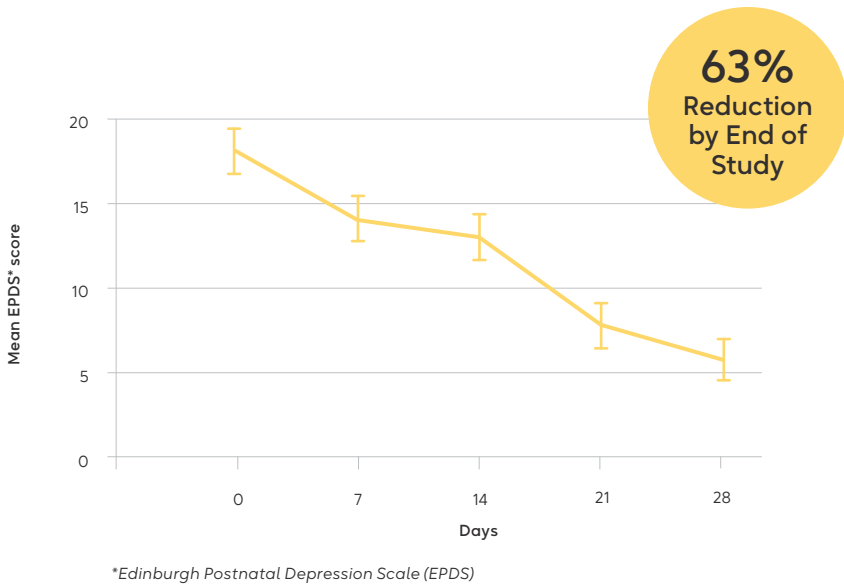
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  - Parental perception of colic severity
  - Parental and family quality of life

# Reduced Maternal Depression

In a prospective, observational multi-centre study, *L. reuteri* Protectis was shown to significantly reduce the maternal depression score in mothers of infants exclusively or predominantly breastfed and supplemented with *L. reuteri* Protectis.<sup>41</sup>



## Study Facts

- Prospective, observational multi-centre study with 120 infants <5 months, diagnosed with colic
- Five drops per day of *L. reuteri* Protectis  $1 \times 10^8$  CFU for 21 days
- Primary outcomes
  - Reduction in crying time
- Secondary outcomes
  - Fussiness, parental perception of colic severity and maternal depression score



# A True Probiotic

At BioGaia we take quality very seriously. Both consumer products and clinical trial material undergo rigorous analyses to always guarantee the highest quality. Our packaging material is carefully selected to maintain the integrity of our bacterial strains, to make sure to deliver on the promise of specific CFU level at end of shelf life.

BioGaia Protectis baby drops fulfills both ISAPP's checklist of a smart probiotic selection and IPA's criteria to qualify microorganisms as "probiotic" in foods and dietary supplements.

- It's backed by science
- It provides an effective dose
- It provides the benefit I'm seeking
- It is safe for me
- It is labeled properly





# BioGaia Protectis® Baby Drops

In 2004, BioGaia launched the world's first probiotic drops for babies. Today, BioGaia Protectis baby drops is sold in over 100 countries, recommended by paediatricians worldwide and recommended in 6 distinguished guidelines.

With over 100 million units sold, our clinically proven BioGaia Protectis baby drops was named:

- 'Best Baby Probiotics' at the UK 2024 Mum Marketplace Awards.
- 'Best Feeding Nursing Product' at the UK 2024 Absolutely Mama Awards
- 'Best Game-changing Parenting Product', at the UK 2024 Dadsnet Awards



## 58 Studies 7 624 Infants

BioGaia Protectis Baby Drops with *L. reuteri* Protectis is the most researched probiotic for management of infant colic<sup>5</sup>.

# Product Facts

## BioGaia Protectis® Baby Drops

Product	Oil drops with neutral taste
Daily dose	5 drops per day.
CFU	One dose contains a minimum of 100 million live <i>L. reuteri</i> Protectis.
Packaging	5- and 10-ml glass bottle or plastic dropper tube.
Strains	Contains one patented bacterial strain, QPS listed and GRAS status.
Name of strain	<i>Limosilactobacillus reuteri</i> DSM 17938
Usage	Suitable from first day of life. Only intended for full-term babies.
Shelf life	24 months in maximum 25°C / 77°F.
Free from	Free from gluten, milk protein and lactose.



# BioGaia Protectis®

## Baby Drops with Vitamin D

Product	Oil drops with neutral taste
Daily dose	5 drops per day with 10 µg Vitamin D. Vitamin D contributes to the normal function of the immune system and is needed for the normal growth and development of bone in children.
CFU	One dose contains 100 million live <i>L. reuteri</i> Protectis.
Packaging	5- and 10-ml glass bottle or plastic dropper tube.
Strains	Contains one patented bacterial strain, QPS listed and GRAS status.
Name of strain	<i>Limosilactobacillus reuteri</i> DSM 17938
Usage	Suitable from first day of life. Only intended for full-term babies.
Shelf life	24 months in maximum 25°C / 77°F.
Free from	Free from gluten, milk protein and lactose.



# Our Probiotic Products

Whether you're looking for probiotics for men or women, babies or children, BioGaia's advanced probiotic products are suitable for everyone and everybody of all ages.

## Adult Health

Gut Health

Immune Health

Oral Health

Bone Health



## Baby & Kids Health

Gut Health

Immune Health

Oral Health



## About Us

Founded in 1990, BioGaia is a Swedish healthcare company, originator and world leader of probiotic food supplements. Our award-winning, clinically proven probiotic products were developed to support the health and wellbeing of people everywhere and throughout every stage of life.

Results from clinical studies with BioGaia's probiotic strains have been published in more than 270 articles in scientific journals, proving them effective and safe in children and adults.

Behind our products, you will find over 200,000 hours of probiotic research. In 2000, we created the world's first probiotic chewable tablet and in 2004, we launched the world's first probiotic drops for babies. Today, our probiotic products are available through local distribution partners in more than 100 countries worldwide.

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