BioGaia Protectis® Baby Drops

Providing Colic Relief Worldwide

Sold in 113 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.[1]

The causes of colic are multi-factorial. Colic is defined as:

- 3 hours of crying per day, for 3 consecutive days
- Presents within 4 months of birth, but typically within the first 2-6 weeks
- The infant has no evidence of failure to thrive, fever, or illness

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.[2] 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.[3]

Additionally, low levels of *Lactobacillus* and *Bifidobacterium* and high levels of *E. coli* have been observed in colicky infants compared to non-colicky infants.[4]

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.[5]

"**Live** microorganisms that, when administered in **adequate amounts**, confer a **health benefit** on the host"[6]

Definition of probiotics

BioGaia Protectis® Baby Drops is Special

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

Reduces crying time by 56%[14]

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

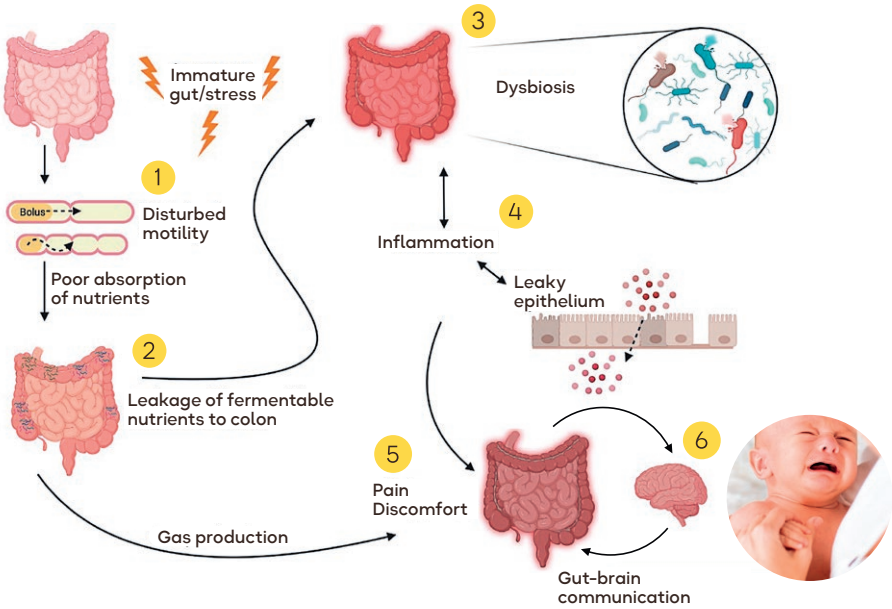


Fig 1. Immaturity of the gastrointestinal tract can lead to distrubed intestinal motility. The motility (1) results in poor absorption of nutrients and leakage of fermentable nutrients (2), giving rise to both increased gas production and dysbiosis (3). The dysbiosis triggers inflammation (4) noticed 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 DSM 17938, 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, enabelling 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.[7] The improved microbial balance[8] subsequently leads to a reduction in inflammation[9] and a reduced leakage by epithelial cells.[10, 11]

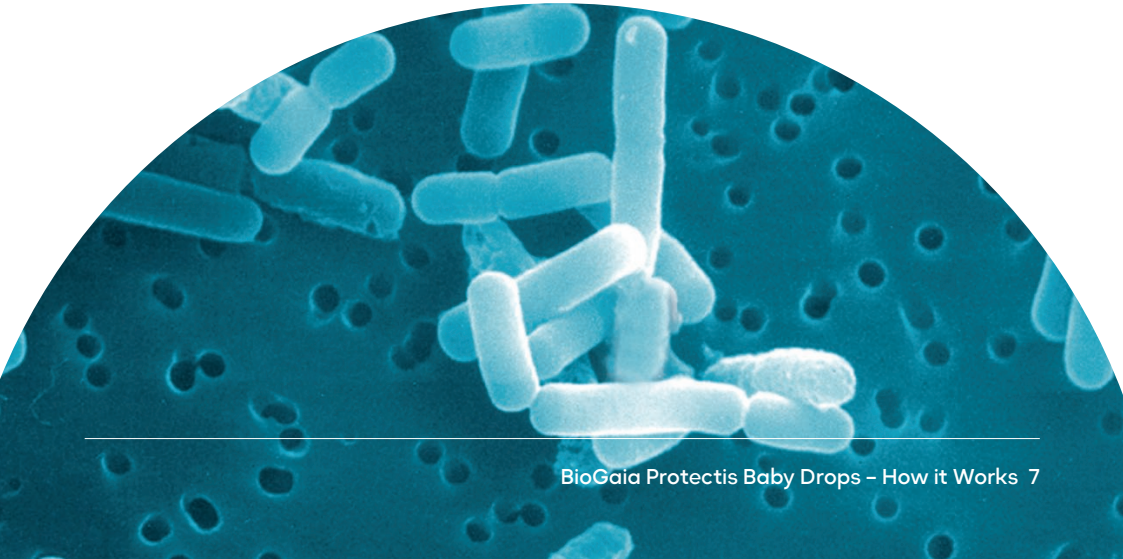
Finally, *L. reuteri* Protectis blocks the pain receptor TRPV-1 leading to reduced nerve firing and reduced pain.[12] Together, these effects may explain the reduced crying in colicky babies.

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.[5] *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.[13]

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 showen a significant reduction in daily inconsolable crying time for babies supplemented with BioGaia Protectis baby drops.

8

Colic Treatment Studies[14-21]

L. reuteri Protectis:

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

2

Colic Prevention Studies[22, 23]

L. reuteri Protectis:

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

12

Meta-analyses[24-35]

L. reuteri Protectis:

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

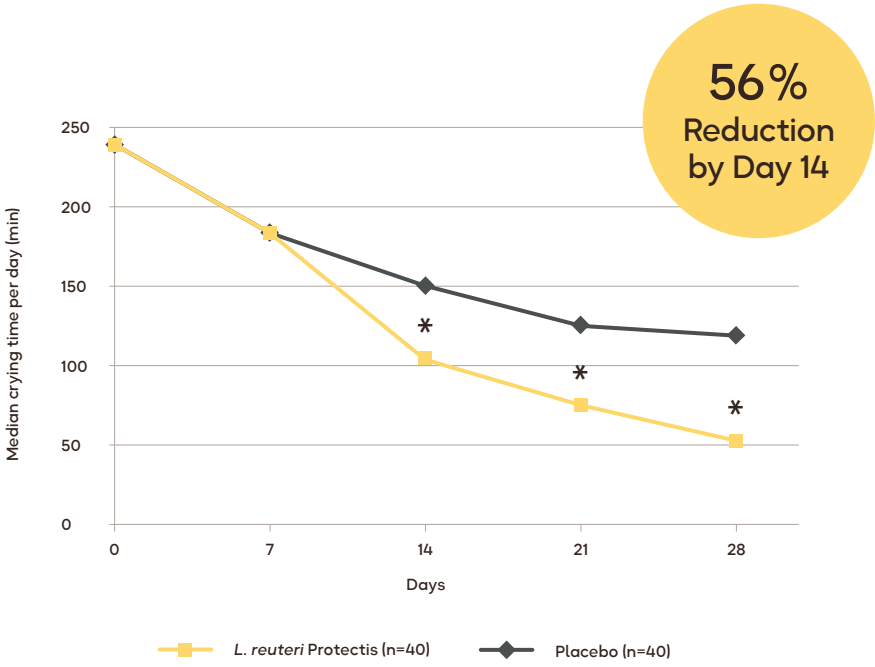
6

International Clinical Guidelines[5, 36-40]

- 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.[14]



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

Study Facts

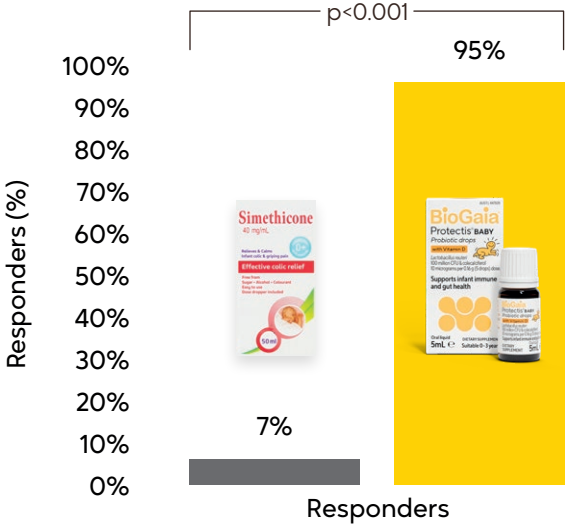
- Double-blind, placebo-controlled, study in 80 exclusively or predominately breastfed colicky infants
- Five drops per day of *L. reuteri* Protectis (n=40) or placebo (n=40) for 21 days
- Primary outcomes
  - Reduction in daily average crying time of ≥50%
  - Crying time in minutes/day at 7, 14, 21 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

Significantly better clinical outcome vs. Simethicone

In the randomised, double-blind study by Savino et al. (2007) showing a 95% positive response to *L. reuteri* vs. only a 7% positive response to Simethicone.

95% of colicky infants responded to *L. reuteri* Protectis treatment

Savino et al. 2007



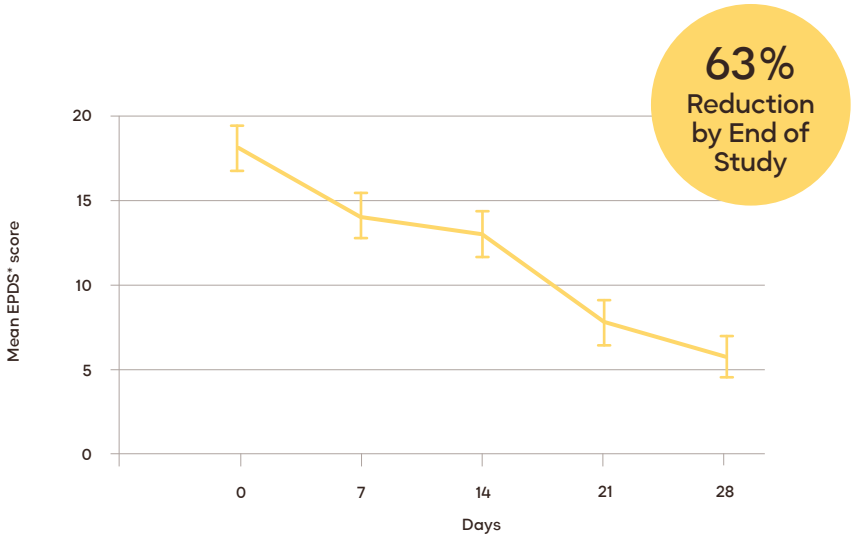
Responder = infant with ≥ 50% reduction in average daily crying time day 28 compared to baseline

Study Facts

- Treatment period 28 days.
- Significantly shorter crying time were seen in the Protectis group.
- It went from >3 hours /day to 51 min/day vs >3 hours/day to 2 h 25 min crying per day in simethicone group.
- Significant more responders (95%) in Protectis arm versus 5% in simethicone.

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.[41]



**Edinburgh Postnatal Depression Scale (EPDS)*

Study Facts

- Prospective, observational multi-centre study with 120 infants <5 months, diagnosed with colic
- Five drops per day of *L. reuteri* Protectis $1x10^8$ 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

Today, BioGaia Protectis baby drops has sold more than 100 million packs in over 113 countries, recommended by paediatricians worldwide and recommended in 6 distinguished guidelines.

57 Studies
7 240 Infants

BioGaia Protectis Baby Drops with *L. reuteri* Protectis is the most researched probiotic for management of infant colic[5].

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 *L. reuteri* Protectis.
Packaging	5ml glass bottle.
Strains	Contains one patented bacterial strain, QPS listed and GRAS status.
Name of strain	*Lactobacillus reuteri* 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 400 IU Vitamin D. Vitamin D contributes to the normal function of the immune system and is needed for the normal growth and development of bones in children.
CFU	One dose contains 100 million live *L. reuteri* Protectis.
Packaging	5ml glass bottle.
Strains	Contains one patented bacterial strain, QPS listed and GRAS status.
Name of strain	*Lactobacillus reuteri* 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.

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Supporting your invisible heroes

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 250 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 in more than 100 countries worldwide..

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