

Reducing constipation

Constipation is one of the most common gastrointestinal conditions affecting 12-27% of the general population.¹ Constipation can be a temporary or chronic problem. Chronic constipation often starts already during childhood.

A widely used diagnostic tool to define chronic constipation are the Rome III criteria. According to these criteria, a patient must have experienced at least 2 of the following symptoms over the preceding 3 months:

- less than 3 bowel movements per week
- straining
- lumpy or hard stools
- sensation of anorectal obstruction
- sensation of incomplete defecation
- manual manoeuvring required to defecate.

There are many risk factors for constipation and the exact cause is often unknown [see figure 1]. Mechanisms thought to play a role are a reduced peristalsis and a shift in the intestinal microbiota.² It is suggested that the intestinal microbiota of constipated

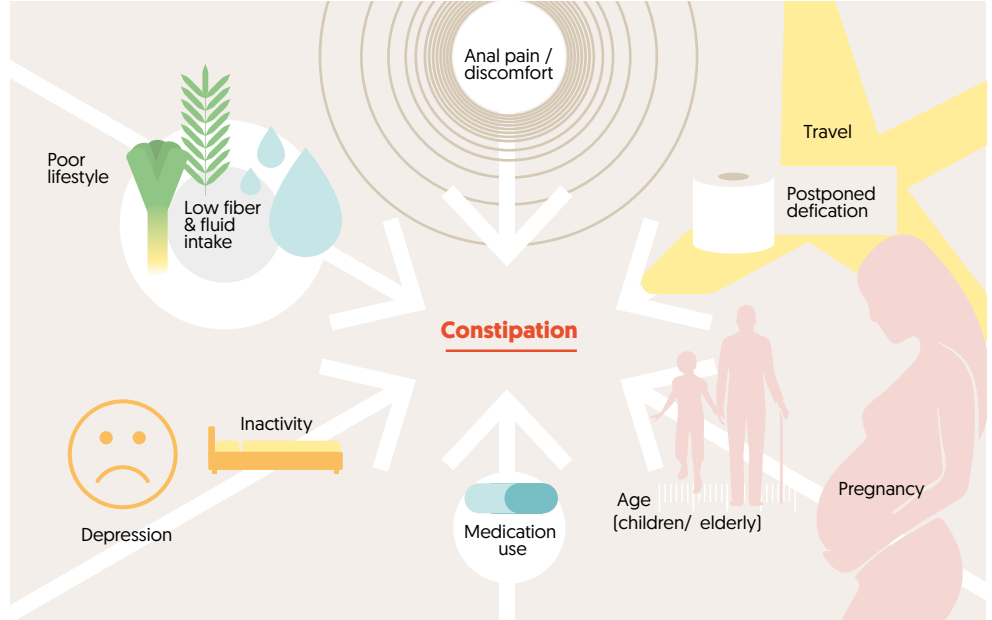


Figure 1: Risk factors for constipation.

persons is in dysbiosis. It, for example, contains higher concentrations of Clostridia and Staphylococci compared to the intestinal microbiota of non-constipated persons³. Currently, [childhood] constipation is often treated with laxatives. Unfortunately, 40% of these children do not react well to this

treatment.⁴ Research has shown that probiotics improve whole gut transit time, stool frequency and stool consistency, and can soften stools by stimulating water- and electrolyte secretion.^{2,5} Therefore, administration of probiotics are a promising and effective therapy for constipation.

Strain selection

Ecologic[®] RELIEF is a multispecies probiotic formulation consisting of 7 specially selected probiotic strains. Probiotic strains can exert health effects at different levels in the gut [see figure 2]. The probiotic strains of Ecologic[®] RELIEF have been selected for their capacity to inhibit pathogen growth and improve motility and peristalsis of the intestine [level 1].

The strains have been screened for their capacity to:

- inhibit *Clostridium difficile* and *Staphylococcus aureus*
- produce lactic acid.

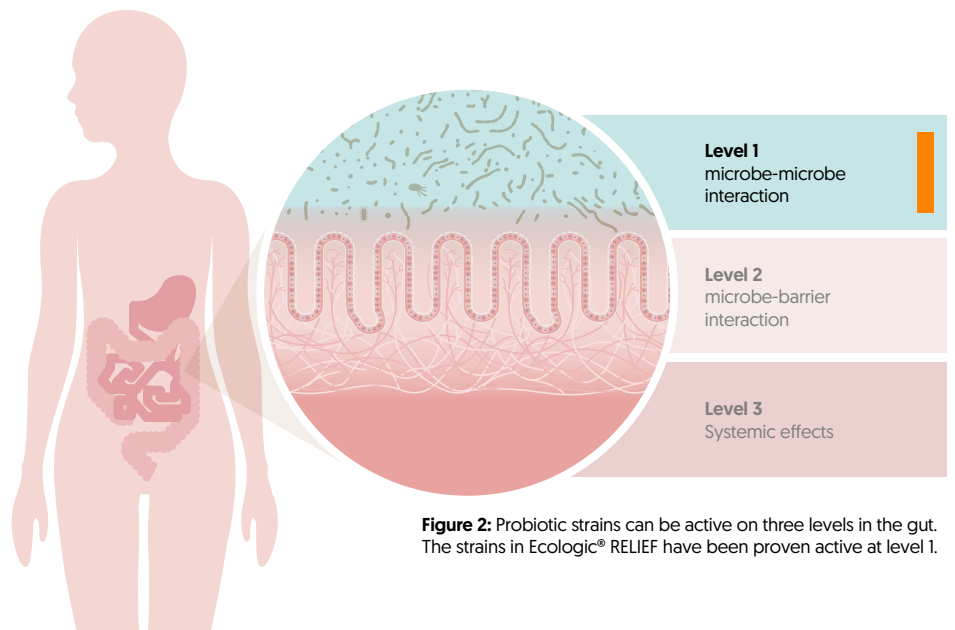


Figure 2: Probiotic strains can be active on three levels in the gut. The strains in Ecologic[®] RELIEF have been proven active at level 1.

Clinical evidence

Ecologic® RELIEF has been tested in a clinical study, in collaboration with the Children's Hospital of the Academic Medical Centre (AMC) of the University of Amsterdam. Twenty children suffering from constipation used Ecologic® RELIEF for four weeks [once daily]. Results showed that **Ecologic® RELIEF significantly increased amount of bowel movements per week, and decreased amount of abdominal pain and faecal incontinence (dirty under-**

wear). No side effects were reported⁶ (see figure 3).

In addition, Ecologic® RELIEF has been tested in an open-label study again in collaboration with the AMC. During this study, 20 pregnant women suffering from constipation as defined by the Rome III criteria consumed 4 grams [1×10^9 CFU/gram] Ecologic® RELIEF daily. Participants recorded daily amongst others, stool frequency and consistency, straining, sensation of incomplete defecation, abdominal pain and adverse events in a standardized bowel diary. **Intake of Ecologic® RELIEF resulted in a significant increase in stool frequency;** from 3.1 at baseline to 6.7 in week four ($p < 0.01$). In addition, compared to baseline, **a significant decrease was found in straining (35%), sensation of incomplete evacuation (50%), sensation of anorectal obstruction (50%) and abdominal pain.** No adverse effects were reported.⁷

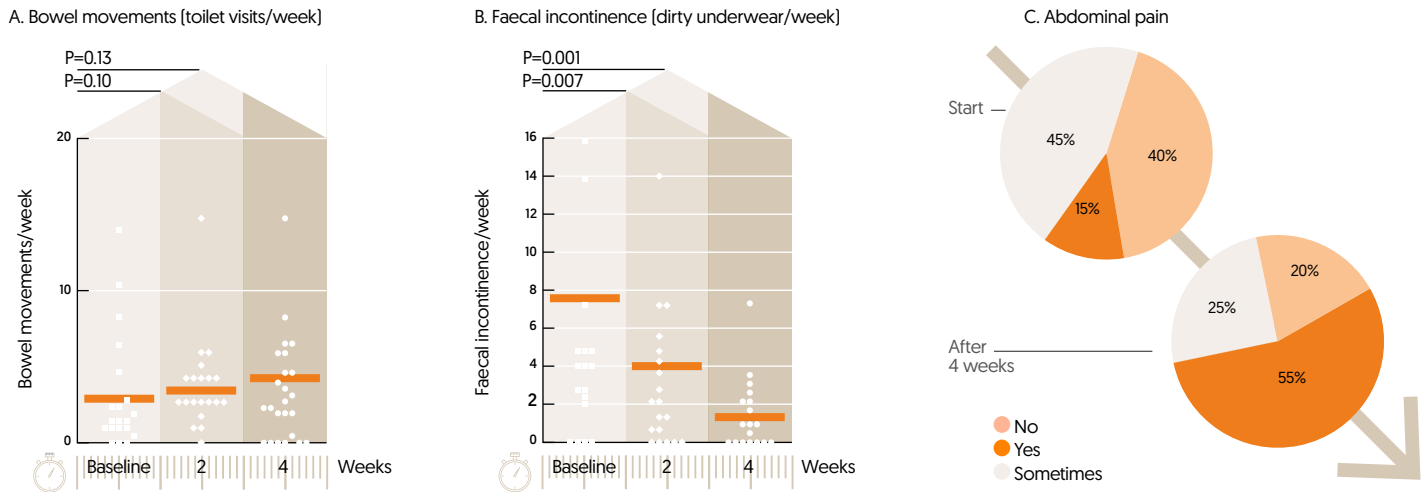






Figure 3: Ecologic® RELIEF is able to significantly increase bowel movements (A), decrease faecal incontinence (B) and decrease abdominal pain (C).

Formulation details

Indication	Reducing constipation.			
Colony forming units (CFU)	1 x 10 ⁹ CFU/gram.			
Recommended daily dosage	4 grams.			
Bacterial strains	<i>B. bifidum</i> W23 <i>B. lactis</i> W51	<i>B. lactis</i> W52 <i>B. longum</i> W108	<i>L. casei</i> W79 <i>L. plantarum</i> W62	<i>L. rhamnosus</i> W71
PROBIOACT® Technology	 Carefully selected ingredients that contribute to stability (shelf-life), GI-survival and metabolic activity of the probiotic strains.			
Treatment period	For as long as desired/needed.			
Storage and stability	2 years stable at room temperature, no refrigeration needed.			
Available dosage forms	Dry powder which can be supplied as bulk or sachets, fully packed (with your design).			
Safety and Quality Profile	  All probiotic strains have the Qualified Presumption of Safety (QPS) status ⁸ . Winclove is a NSF International Certified GMP Facility for manufacturing dietary supplements and is ISO 22000:2005 certified for the development and production of pre- and probiotics.			
Marketing	 Medically endorsed under private label on a co-branding basis. Co-branding enables our business partners to use the scientific data in their marketing communication.			

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Ecologic® RELIEF publications

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This information is intended for business professionals only, not for consumers.

The formulations contained herein are concepts, not commercially available and not intended to diagnose, cure or prevent any diseases.