




Regflor®

Lyophilized *Bifidobacterium infantis*
8x10⁸ CFU / Capsule

• Relieves IBS Overall Symptoms and Improves Quality of Life

• Regulation of Gut Microbiota without Primary Bloating

25°C  No Need to be Refrigerated

✓ Efficacy Assurance of Regflor®



1. **Resistant to Gastric Acid and Bile Compounds** ^{1,2,3,4}





2. **Freeze Drying Manufacturing Method:** According to The United States Pharmacopeia (USP), freeze drying maintains cell viability more than other methods during transferring or storage periods ⁵



3. **Single Strain Probiotic at a Low Dose:** Appears to be more effective in improving overall IBS symptoms ⁶



4. **Evidence Based Health Benefits:** *B. infantis* has been demonstrated in the two largest, properly controlled clinical trials ⁷

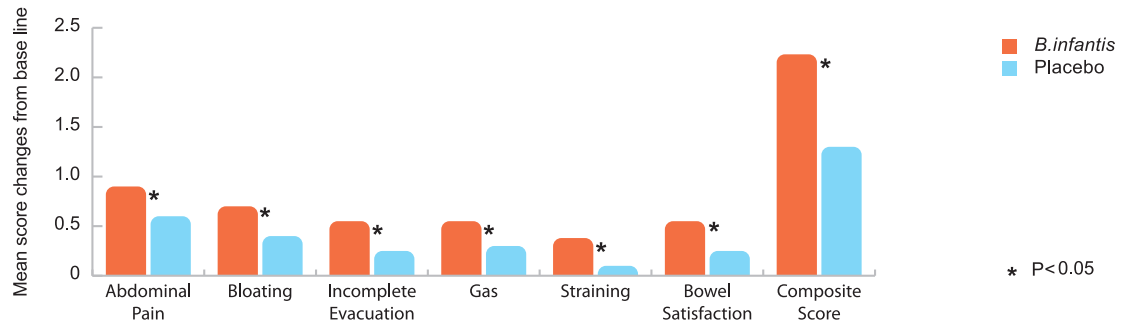
Global Guidelines ^{8,9}	Adults Disorder Action	Probiotic Strain	Evidence Level
	Improvement in subjects global assessment of IBS symptoms	<i>Bifidobacterium infantis</i> 10 ⁸ CFU, Once daily	2
 The European Society for Primary Care Gastroenterology	Helps relieve overall symptom burden in some patients with IBS	<i>Bifidobacterium infantis</i>	High
	Helps reduce abdominal pain in some patients with IBS	<i>Bifidobacterium infantis</i>	High
	Helps reduce bloating/distension in some patients with IBS	<i>Bifidobacterium infantis</i>	Moderate
	Helps improve frequency and/or consistency of bowel movements in some patients with IBS	<i>Bifidobacterium infantis</i>	Moderate
	Has a favorable safety profile in patients with a range of lower GI symptoms typically managed in primary care or general practice	<i>Bifidobacterium infantis</i>	High

✓ Safety Assurance of Regflor®

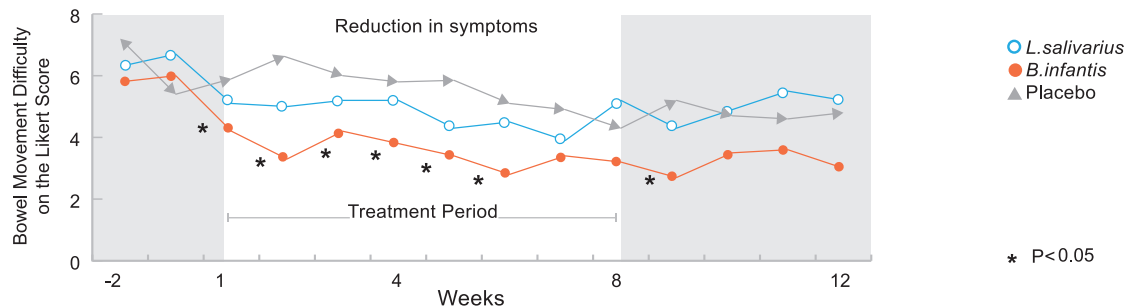


• **Antimicrobial Resistance Assessment of a Bacterial Strain Used as Probiotics:** We checked all bacterial strains for having acquired resistance to antimicrobials that is shown to be due to the acquisition of genetic determinants, according to Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA ^{10,11}

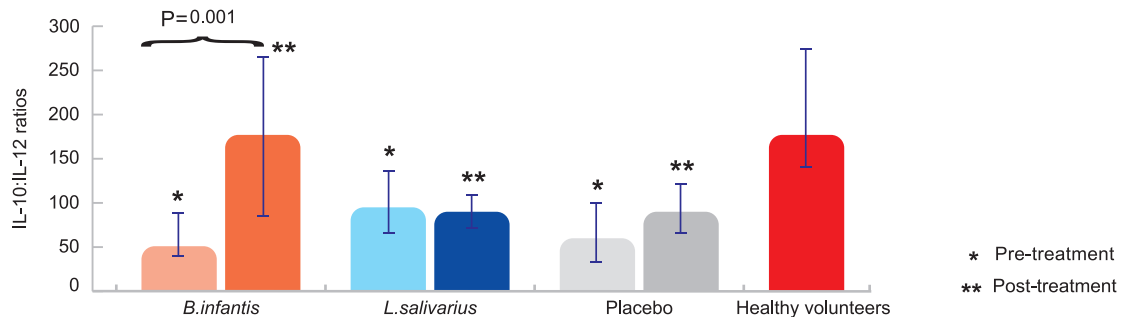
Significant improvement IBS symptoms is achieved in the *B. infantis* group after 4 weeks treatment ⁴



B. infantis alleviates symptoms in IBS, while the *L. salivarius* strain does not ¹²



Following *B. infantis* used, IL-10 / IL-12 ratios in the IBS subjects become similar to the levels in the healthy volunteers ¹²



Description

Each Regflor[®] capsule contains 200 mg lyophilized live friendly bacteria, *Bifidobacterium infantis*, (8×10^8 CFU).

Indication

Regflor[®] capsule is indicated in adults (≥ 12 years) for :

- Decreasing Irritable Bowel Syndrome (IBS) symptoms

Dosages and duration of administration

- Adults, take 1 capsule daily or as directed by physician.
- For the best results, it is recommended to take Regflor[®] capsule up to 2 months.

Direction for usage

- Regflor[®] capsule should be used with full glass of water, with or without foods.

Side effects

- No common side effect has been reported for the use of Regflor[®] capsule.
- A severe allergic reaction with this product is rare but if you experience itching, swelling, severe dizziness and respiratory problems consult with your healthcare practitioner immediately.

Interaction with other medications and foods

- No interaction has been reported for the use of Regflor[®] capsule but if antibiotics are being used at the same time, take at least 2-3 hours before or after taking antibiotics.
- Regflor[®] capsule has no interaction with foods.

Pregnancy and Lactation

- Probiotics are safe during pregnancy and lactation but it is better to take probiotics when needed. Consult with your healthcare practitioner about benefits and risk of probiotics during pregnancy and lactation.

Storage condition

- Store in a cool and dry place (below 25°C). No need to be refrigerated.

References

- Ipek Goktepe, Vijay K. Juneja, Mohamed Ahmedna. Probiotics in Food Safety and Human Health, by Taylor & Francis Group, LLC; 2006.
- Probiotic microorganisms-Specifications and In Vitro test methods. Iranian National Standardization Organization; 2014.
- Colum Dunne, et al. In vitro selection criteria for probiotic bacteria of human origin: correlation with in vivo findings. Am J Clin Nutr 2001; 73(suppl):386S-92S.
- Darren M, et al. Bifidobacterium infantis 35624: A Novel Probiotic for the Treatment of Irritable Bowel Syndrome. Rev Gastroenterol Dis. 2009; 9(1):7-15.
- USP-42.
- Yan Zhang, et al. Effects of probiotic type, dose and treatment duration on irritable bowel syndrome diagnosed by Rome III criteria: a meta-analysis. BMC Gastroenterology (2016) 16:62.
- Joint FAO/WHO Working Group. 2002. Guidelines for the Evaluation of Probiotics in Food, FAO/WHO.
- Probiotics and prebiotics, World Gastroenterology Organization Global Guidelines, February 2017.
- Hungin AP, et al. Systematic review: probiotics in the management of lower gastrointestinal symptoms in clinical practice – an evidence-based international guide. Aliment Pharmacol Ther 2013; 38(8):864-86.
- Opinion of the Scientific Committee on a request from EFSA on the introduction of a Qualified Presumption of Safety (QPS) approach for assessment of selected microorganisms referred to EFSA. The EFSA Journal (2007) 587, 1-16.
- EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), Guidance on the characterization of microorganisms used as feed additives or as production organisms. EFSA Journal 2018; 16(3):5206, 24 pp.
- O'Mahony L. Lactobacillus and bifidobacterium in irritable bowel syndrome: symptom responses and relationship to cytokine profiles. Gastroenterology. 2005; 128:541-551.