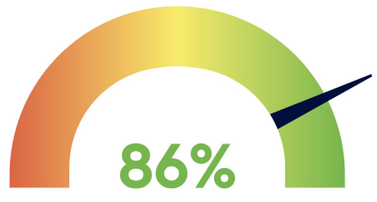
# B. coagulans Unique IS-2

| Bacillus | coagulans | Unique IS-2 (MTCC 5260, ATCC PTA-11748) |
|---|---|---|
| GENUS | SPECIES | STRAIN |

## Summary

Of all the probiotics we assessed, Bacillus coagulans Unique IS-2 was a true stand out. This probiotic was tested in two randomized, placebo-controlled trials—one with children (1) (n = 141) and another with adults2 (n = 108). Both studies provided Bacillus coagulans Unique IS-2 at a dose of 2 billion colony-forming units (CFU) per day for 8 weeks, evaluating symptoms such as bowel habits, overall IBS symptom severity, and abdominal pain intensity. **Continues next page...**

Evidence Quality Grade




| SYMPTOM | IMPROVEMENT | # PARTICIPANTS | STUDIED DOSE |
|---|---|---|---|
| Diarrhea | STRONG | 249 | 2 billion CFU |
| Constipation | STRONG | 249 | 2 billion CFU |
| Bowel Habits | STRONG | 249 | 2 billion CFU |
| Global IBS Symptoms | STRONG | 249 | 2 billion CFU |
| Abdominal Pain /... | STRONG | 249 | 2 billion CFU |
| Bloating / Distension | STRONG | 249 | 2 billion CFU |
| Gas / Flatulence | STRONG | 249 | 2 billion CFU |
| Nausea / Vomiting | NOT STUDIED | 0 | N/A |
| Mental Health | NOT STUDIED | 0 | N/A |

## Dosing

| | |
|---|---|
| Potentially Effective Doses(s) | 2 billion CFU/day |
| Form | Capsule or Chewable tablet |
| Suggested Minimum Trial Duration | 8 weeks |

## How to select a product

Many commercial products contain this strain. But not all are suitable. You need to find one that:

1. has a transparent formula, so we know what is in it and how much
2. only contains active ingredients that are probiotic strains, which have been clinically studied in IBS populations
3. can deliver the studied dose
4. has undergone 3rd party testing for active ingredient and potency, as well as microbiological testing, heavy metals analysis and allergen testing

Search **probioticfinder.org** to see which products match this criteria.

## Notes:

## Why Did Unique IS-2 Catch Our Attention?

1. **High Bar for Probiotic Responders and High Rate of Responders**
   In both studies, participants were considered probiotic responders if they showed an improvement in abdominal pain intensity of ≥50% from baseline. This is a tougher criterion than the ≥30% improvement in abdominal pain recommended by the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for IBS drug trials.(3,4) Despite this high bar, Bacillus coagulans Unique IS-2 delivered impressive results, with around 85%-93% of participants across both studies in the probiotic groups meeting this responder threshold.

2. **Quality Evidence and Broad Symptom Relief**
   Bacillus coagulans Unique IS-2 showed strong and consistent effects in managing several IBS symptoms in both children and adults (more details below). Our independent review rated both studies in our highest evidence quality tier, and all effect sizes we calculated (Cohen's d or h) were in the top 2-25% of beneficial effect sizes in our entire database. P-values compared to placebo were highly significant (< 0.001), indicating a very low probability that the observed results were due to chance.

## Additional Significant Improvements

- Stool Consistency: From the 6th week onwards, 38 out of 72 children attained normal stool consistency1 (Cohen's h = 0.73). In adults, 65% (36/53) achieved normal stool consistency, significantly higher than the placebo group (Cohen's h = 0.83; $p < 0.001$).(2)
- Bowel Habit Satisfaction (adults): Bowel habit satisfaction improved by 57.6% (Cohen's d = 1.84), significantly higher than the placebo group ($p < 0.0001$).(2)
- Symptom Relief (Children): There were significant improvements on the Subject's Global Assessment of Relief (SGARC) scale compared to placebo ($p < 0.0001$, Cohen's d = 2.08).(1)
- Family Impact (Children): Significant improvement in the family's assessment of the impact of their child's IBS on family life ($p < 0.0001$) compared to placebo.(1)
- Patient Global Assessment (Adults): In the probiotic group, 18.87% of patients experienced complete relief, and 64.15% had considerable relief, both significantly higher than the placebo group (Cohen's h = 1.62; $p < 0.0001$).(2)
- Physician Global Assessment (Adults): In the probiotic group, 20.75% of patients experienced complete relief, and 58.49% had considerable relief, both significantly higher than the placebo group (Cohen's h = 1.52; $p < 0.0001$).(2)

## Were There Subtype-Specific Effects?

In both studies, no subtype-specific analysis was conducted, so the results are generalized across the subtypes assessed.

In the children's study, the population was mainly IBS-C (51.77%), followed by IBS-D (41.13%) and IBS-M (7.24%).(1)

In the adult study, the population consisted of IBS-M (66.04%) and IBS-C (33.96%), with no IBS-D participants.(2) It's possible that Bacillus coagulans Unique IS-2 may have therapeutic effects in IBS-D, IBS-C, and IBS-M populations, though future subtype-specific studies would help in confirming these benefits.

## Key Takeaways

- Available evidence suggests that Bacillus coagulans Unique IS-2 is a promising probiotic candidate for managing a broad range of IBS symptoms, including abdominal pain, incomplete evacuation, global IBS symptoms, abnormal bowel habits, bloating/distention, and flatulence.
- The studies on this probiotic fell into our highest tier for evidence quality, and the composite beneficial effects all fell into our strongest effect size category of ≥ 1.0.
- Overall, Bacillus coagulans Unique IS-2 has shown great potential for improving IBS symptoms across diverse IBS populations.

This handout provides educational content on probiotics, derived from clinical studies, for both clinicians and their patients over the age of 18. The information is intended to enrich professional knowledge and practice but does not constitute medical advice, diagnosis, or treatment. Always consult with medical professionals before making any changes to exercise, nutrition, or supplementation regimens.

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## References

1. Sudha MR, Jayanthi N, Aasin M, et al. Efficacy of Bacillus coagulans Unique IS2 in treatment of irritable bowel syndrome in children: a double blind, randomised placebo controlled study. Benef Microbes 2018;9(4):563–72. doi: 10.3920/BM2017.0129.
2. Madempudi RS, Ahire JJ, Neelamraju J, et al. Randomized clinical trial: the effect of probiotic Bacillus coagulans Unique IS2 vs. placebo on the symptoms management of irritable bowel syndrome in adults. Sci Rep 2019;9:12210. doi: 10.1038/s41598-019-48554-x.
3. U.S. Food and Drug Administration. Irritable Bowel Syndrome: Clinical Evaluation of Products for Treatment. FDA website. Accessed July 22, 2024.
4. European Medicines Agency. Guideline on the Evaluation of Medicinal Products for the Treatment of Irritable Bowel Syndrome (Revision 1). EMA website. Accessed July 22, 2024.