

# ProbioSpore



1 Vegetarian Hard Capsule

Relieves abdominal pain associated with medically diagnosed IBS and improves bowel regularity

## OVERVIEW

- > Utilises *Bacillus coagulans* (UNIQUE IS-2™) spore-based technology
- > Supports beneficial intestinal flora and healthy digestion
- > Relieves abdominal pain associated with medically diagnosed irritable bowel syndrome
- > Helps improve bowel regularity

### Active Ingredients (per vegetarian hard capsule)

*Bacillus coagulans* (Unique IS-2™) 4 billion CFU

**Pack Size** 60

**Serving Per Pack** 60

### Excipients

Maltodextrin  
Microcrystalline cellulose  
Colloidal anhydrous silica  
Magnesium stearate

### Directions for Use

Adults, take one capsule daily with water or as advised by your health professional

### Allergen Information

No added: Gluten, dairy, lactose or nuts

### Prescribing Information:

*Bacillus coagulans* preparations usually contain live and active organisms. Therefore, simultaneously taking antibiotics might kill a significant number of the organisms. Tell patients to separate administration of antibiotics and *B. coagulans* preparations by at least two hours.

### Warnings

- The TGA advises that *Bacillus coagulans* is not suitable for children.
  - *Bacillus coagulans* may affect the way some medicines work, including immunosuppressants. Consult your health professional before taking with other medicines. If symptoms persist or worsen talk to your medical practitioner.
  - Contains soya bean products.
- When using to improve bowel regularity the TGA advises:**
- To drink plenty of water.
  - To not use when abdominal pain, nausea or vomiting are present or if you develop diarrhoea.
  - To seek the advice of a healthcare professional before taking this product if you are pregnant or breastfeeding.

Designed and packed in Australia from imported ingredients.



No Added Gluten



No Added Dairy



No Added Nuts



Vegan Friendly



## EDUCATION

Designs for Health ProbioSpore is a unique spore-based probiotic containing *Bacillus coagulans* (UNIQUE IS-2™) as a single ingredient.

Originally named *Lactobacillus sporogenes*, *Bacillus coagulans* is a transient, gram positive, lactic acid producing bacteria that is protected from stomach acid by a protein-based spore coating. Instead of dying off as a result of coming into contact with stomach acid, the spore coating expands and *B. coagulans* begins to germinate as it moves out of the stomach and into the duodenum where the environment is more amenable.<sup>1,2</sup> Germination occurs between 4-6 hours after ingestion, and around 85-93% of the ingested and germinated probiotic ends up in the intestines.<sup>1,2</sup> Further to this, its preferred growth temperature is between 35-50°C.<sup>2</sup> As a result, *B. coagulans* displays an excellent stability profile at ambient temperatures.

Once germination has taken place, *B. coagulans* proliferates in the distal parts of the small intestine and is able to produce the isomeric form of lactic acid. The isomeric form is unlikely to give rise to metabolic acidosis.<sup>1</sup>

Being a transient and not a colonising probiotic, *B. coagulans* does not remain in the intestinal tract for long and begins to be excreted via the faeces around seven days after supplementation ceases.<sup>1</sup> Despite such a short period of time of activity in the bowel, *B. coagulans* affects the microbial colony in that it helps to regulate beneficial flora and inhibit the proliferation of opportunistic bacteria via the production of “bacteriocin-like substances” and short chain fatty acids (SCFAs). These compounds support the health of the GI lining and provide direct antagonism to microbial pathogens.<sup>1</sup>

### *Bacillus Coagulans* and digestion

*B. coagulans* is also able to produce several enzymes that assist digestive processes such as nutrient breakdown and absorption. Some of these enzymes include lipase, protease,  $\alpha$ -amylase and both  $\alpha$ - &  $\beta$ -galactosidase and assist with protein and carbohydrate digestion.<sup>2</sup> Absorption is also facilitated as *B. coagulans* can reduce inflammation of the gut lining and promote the health of the permeable areas of the micro villi.<sup>2</sup>

### Bowel regularity

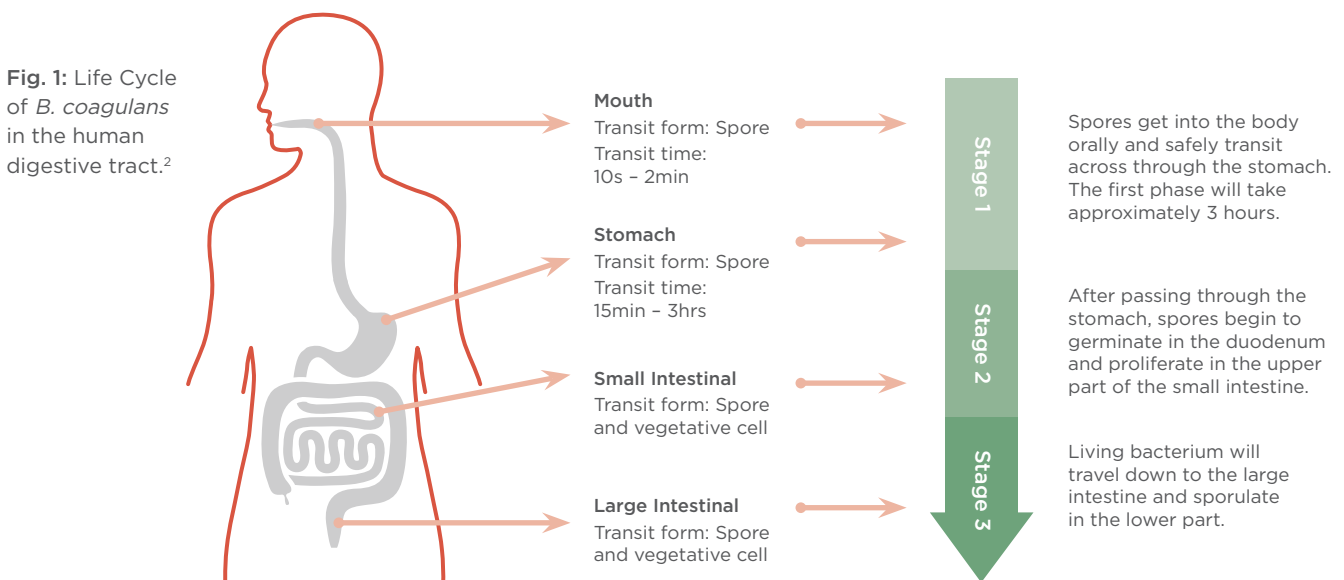
As well as digestion, *B. coagulans* has also been found to assist excretion. It produces metabolites such as diacetyl, SCFAs and vitamins, stimulates peristalsis, reduces amine production, reduces bowel transit time, and improves the overall health of the bowel. This in turn helps to improve bowel regularity and reduce toxin build up.<sup>2,3</sup>

A randomised, double-blind, placebo-controlled clinical trial performed using the Unique IS-2™ strain on 100 men and women suffering from functional constipation showed that supplementation with *B. coagulans* at a dose of 2bn cfu daily improved stool frequency, consistency, pain associated with defecation, and feelings of incomplete evacuation.<sup>3</sup>

### Pain associated with Irritable Bowel Syndrome

The specific strain Unique IS-2™ has also been the subject of a clinical trial included in a meta-analysis for its effects on medically diagnosed irritable bowel syndrome.<sup>4,5</sup>

Daily dosing of 2 billion CFU of Unique IS-2™ daily was studied in a randomised, double-blind, placebo-controlled trial involving 108 men and women fulfilling ROME III criteria for irritable bowel syndrome. Reduction of abdominal pain and an increase in spontaneous complete bowel movements were the primary endpoints studied.



*Bacillus coagulans* Unique IS-2™ was able to show more than a 50% pain reduction score in 90.5% of patients, and significantly reduced the total symptom severity score (including symptoms such as bloating, incomplete evacuation, urgency, straining, passage of gas, bowel habit satisfaction and stool consistency) from 26.7 to 10.6 (placebo 26.7 to 21.5) over the course of eight weeks.<sup>4</sup>

A meta-analysis picked up this trial as well as 41 others done on a number of different probiotic species and concluded that *Bacillus coagulans* Unique IS-2™ is able to effectively reduce abdominal pain associated with medical diagnosed irritable bowel syndrome.<sup>5</sup>

**References supplied on request.**

### Designs for Health Quality Guarantee

Designs for Health medicines that are listed on the Australian Register of Therapeutic Goods will display an AUSTL number on the label. Listed medicines in Australia need to be manufactured according to legislated standards set out in Therapeutic Goods Order 101. TGO101 legislation sets out minimum quality standards for medicines supplied in Australia that display an AUSTL number. It mandates testing for:

- Impurities such as heavy metals (including lead, mercury, cadmium and arsenic), pesticides and residual solvents
- Dissolution (to ensure the capsule will dissolve once taken)
- Uniformity (to ensure that every capsule is the same)

Final assay testing is also performed to ensure that what we have on the label is in each capsule, and microbiological testing is performed to ensure that no microbial contamination has occurred during the encapsulation and packing process.