



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

|                                |                                                                     |                        |
|--------------------------------|---------------------------------------------------------------------|------------------------|
| <b>Summary for ARTG Entry:</b> | 390339                                                              | THER-BIOTIC IBS Relief |
| <b>ARTG entry for</b>          | Medicine Listed                                                     |                        |
| <b>Sponsor</b>                 | SFI Australasia                                                     |                        |
| <b>Postal Address</b>          | Level 2 / 170 Pacific Highway, St. Leonards, NSW, 2065<br>Australia |                        |
| <b>ARTG Start Date</b>         | 14/06/2022                                                          |                        |
| <b>Product Category</b>        | Medicine                                                            |                        |
| <b>Status</b>                  | Active                                                              |                        |
| <b>Approval Area</b>           | Listed Medicines                                                    |                        |

### Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

### Products

#### 1 . THER-BIOTIC IBS Relief

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 14/12/2023 |
|---------------------|-------------------------|-----------------------|------------|

### Permitted Indications

Relief of symptoms of medically diagnosed Irritable Bowel Syndrome

- Linked indication - Relieve digestive discomfort
- Linked indication - Decrease/reduce/relieve abdominal pain/discomfort
- Linked indication - Helps reduce occurrence of abdominal bloating
- Linked indication - Decrease/reduce/relieve abdominal bloating/distention
- Linked indication - Decrease/reduce/relieve gastrointestinal pain
- Linked indication - Maintain/support general health and wellbeing
- Linked indication - Decrease/reduce/relieve flatulence/carminative

Relief of symptoms of medically diagnosed Irritable Bowel Syndrome

Help reduce occurrence of symptoms of medically diagnosed Irritable Bowel Syndrome

Maintain/support intestinal health in healthy adults

Maintain/support intestinal good/beneficial/friendly flora in healthy adults

Maintain/support gastrointestinal system health in healthy adults

### Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Product presentation must only refer to medically diagnosed IBS.

Label statement: If symptoms persist or worsen talk to your medical practitioner.

Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

Not suitable for children.

Bacillus coagulans may affect the way some medicines work, including immunosuppressants. Consult your health professional before taking with other medicines (or words to that effect)



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|                                      |                 |
|--------------------------------------|-----------------|
| Additional Product information       |                 |
| Pack Size/Poison information         |                 |
| Pack Size                            | Poison Schedule |
| Components                           |                 |
| 1 . Formulation 1                    |                 |
| Dosage Form                          | Capsule, hard   |
| Route of Administration              | Oral            |
| Visual Identification                |                 |
| Active Ingredients                   |                 |
| Bacillus coagulans                   | 2 billion CFU   |
| Lactobacillus plantarum              | 20 billion CFU  |
| Other Ingredients (Excipients)       |                 |
| calcium hydrogen phosphate dihydrate |                 |
| colloidal anhydrous silica           |                 |
| hypromellose                         |                 |
| magnesium stearate                   |                 |
| microcrystalline cellulose           |                 |
| potable water                        |                 |

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