



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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

Product Type	Single Medicine Product	Effective Date	14/06/2022
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Permitted Indications

Decrease/reduce/relieve constipation in healthy adults
Maintain/support bowel regularity in healthy adults
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
Linked indication - Decrease/reduce/relieve abdominal bloating/distention
Linked indication - Decrease/reduce/relieve flatulence/carminative
Linked indication - Promote/increase bowel evacuation
Linked indication - Maintain/support general health and wellbeing
Linked indication - Helps reduce occurrence of abdominal bloating
Linked indication - Decrease/reduce/relieve gastrointestinal pain
Linked indication - Relieve digestive discomfort
Linked indication - Decrease/reduce/relieve abdominal pain/discomfort
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

Product presentation must only refer to medically diagnosed IBS.
Label statement: Drink plenty of water (or words to that effect).
Label statement: If symptoms persist or worsen talk to your medical practitioner.

Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.
Label statement: Do not use when abdominal pain, nausea or vomiting are present or if you develop diarrhoea. If you are pregnant or breastfeeding - seek the advice of a healthcare professional before taking this product (or words to that effect).
Product presentation must not refer to or imply weight loss.
Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to gastro oesophageal reflux disease.

Standard Indications



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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)

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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