



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	384635	Ther-Biotic Well Mood
ARTG entry for	Medicine Listed	
Sponsor	SFI Australasia	
Postal Address	Level 2 / 170 Pacific Highway, St. Leonards, NSW, 2065 Australia	
ARTG Start Date	24/02/2022	
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 Well Mood

Product Type	Single Medicine Product	Effective Date	1/06/2022
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Permitted Indications

- Maintain/support intestinal health
- Maintain/support intestinal good/beneficial/friendly flora
- Maintain/support gastrointestinal system health
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Helps stimulate a healthy immune system response
- Aids/assists the body to cope with environmental stress
- Support healthy stress response in the body
- Calms the mind
- Help maintain/support emotional wellbeing
- Decrease/reduce/relieve restlessness/excess nervous energy
- Decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve symptoms of stress
 - Linked indication - Decrease/reduce/relieve abdominal pain/discomfort
 - Linked indication - Maintain/support learning and information processing
 - Linked indication - Maintain/support cognitive function/mental function
 - Linked indication - Decrease/reduce/relieve nausea
- Decrease/reduce/relieve nervous tension/unrest
- Decrease/reduce/relieve symptoms of mild anxiety
- Support healthy emotional/mood balance

Indication Requirements

- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must only refer to mild anxiety.
- 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

No Warnings included on Record

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

Bifidobacterium longum 300 million CFU

Lactobacillus helveticus 2.7 billion CFU

Lactobacillus plantarum 1 billion CFU

Other Ingredients (Excipients)

ascorbic acid

colloidal anhydrous silica

gellan gum

hypromellose

magnesium stearate

maize starch

maltodextrin

microcrystalline cellulose

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