Public Summary

Summary for ARTG Entry:	384639 THER-BIOTIC BioDaily
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 BioDaily

Product Type Single Medicine Product **Effective Date** 17/06/2022

Permitted Indications

Maintain/support bowel regularity

Decrease/reduce/relieve bowel discomfort

Helps reduce occurrence of symptoms of traveller's diarrhoea

Maintain/support healthy bowel/colon function

Maintain/support intestinal health

Maintain/support healthy digestive system function

Maintain/support intestinal good/beneficial/friendly flora

Maintain/support intestinal good/beneficial/friendly flora in elderly individuals

Helps maintain/support good/beneficial/friendly gut flora during antibiotic use

Helps restore good/beneficial/friendly intestinal/gut/bowel flora

Maintain/support gastrointestinal system health

Maintain/support healthy gastrointestinal function

Decrease/reduce/relieve abdominal bloating/distention

Maintain/support healthy immune system function

Indication Requirements

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

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

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: Drink plenty of water (or words to that effect).

Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).

Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

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 animalis ssp lactis	**2 billion CFU**
Bifidobacterium animalis ssp lactis	**2.5 billion CFU**
Bifidobacterium breve	**2.5 billion CFU**
Bifidobacterium lactis	**2 billion CFU**
Lactobacillus plantarum	**2.5 billion CFU**
Saccharomyces cerevisiae (Boulardii)	**10 billion CFU**

Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
magnesium stearate
microcrystalline cellulose
sorbitan monolaurate