Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	334455 SB 5B
ARTG entry for	Medicine Listed
Sponsor	Natural Bio Pty Limited
Postal Address	PO Box 384, MONA VALE, NSW, 1660 Australia
ARTG Start Date	17/04/2020
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 . SB 5B

Product Type Single Medicine Product **Effective Date** 22/11/2022

Permitted Indications

Maintain/support general health and wellbeing

Decrease/reduce/relieve diarrhoea

Helps reduce occurrence of diarrhoea

Helps reduce occurrence of symptoms of traveller's diarrhoea

Relief of symptoms of medically diagnosed Irritable Bowel Syndrome

Maintain/support digestive system health

Maintain/support healthy immune system function

Maintain/support healthy gastrointestinal immune function

Indication Requirements

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

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.

Product presentation must only refer to medically diagnosed IBS.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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 3-6 years or 48 hours in adults and children over 6 years, seek medical advice (or words to that effect).

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

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Pack Size/Poison information	
Pack Size	**Poison Schedule**

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients	
Saccharomyces cerevisiae (Boulardii)	**250 mg**

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
carrageenan
colloidal anhydrous silica
hypromellose
iron oxide yellow
magnesium stearate
microcrystalline cellulose
potassium acetate
purified water
sorbitan monostearate
titanium dioxide

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