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**	14/09/2023

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

Maintain/support healthy digestive system function

Maintain/support digestive system health

Maintain/support intestinal good/beneficial/friendly flora

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

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

Maintain/support healthy immune system function

Maintain/support healthy gastrointestinal immune function

Indication Requirements

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

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).

Additional Product information

Produced at 03.01.2024 at 04:19:26 AEDT

Public Summary

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

Public Summary

Page 2 of 2   Produced at 03.01.2024 at 04:19:26 AEDT

This is not an ARTG Certificate document.
The onus is on the reader to verify the current accuracy of the information on the document subsequent to the date shown.
Visit www.tga.gov.au for contact information