



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	328696	MULTIBIOTIC
ARTG entry for	Medicine Listed	
Sponsor	Natural Bio Pty Limited	
Postal Address	PO Box 384, MONA VALE, NSW, 1660 Australia	
ARTG Start Date	16/01/2020	
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 . MULTIBIOTIC

Product Type	Single Medicine Product	Effective Date	3/04/2024
---------------------	-------------------------	-----------------------	-----------

Permitted Indications

Maintain/support general health and wellbeing
Decrease/reduce/relieve excess intestinal gas
Maintain/support intestinal health
Maintain/support healthy mucous linings of the digestive system
Maintain/support digestive system health
Maintain/support intestinal good/beneficial/friendly flora
Helps maintain/support good/beneficial/friendly gut flora during antibiotic use
Help restore good/beneficial/friendly gut flora after antibiotic use
Helps restore good/beneficial/friendly intestinal/gut/bowel flora
Maintain/support gastrointestinal system health
Decrease/reduce/relieve abdominal bloating/distention
Relieve digestive discomfort
Maintain/support immune system health
Maintain/support healthy immune system function

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to gastro oesophageal reflux disease.
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 symptoms persist consult your healthcare practitioner (or words to that effect).

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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	3 billion CFU
Bifidobacterium bifidum	500 million CFU
Bifidobacterium breve	1.75 billion CFU
Lactobacillus acidophilus	3.75 billion CFU
Lactobacillus plantarum	1.575 billion CFU
Lactobacillus rhamnosus	9 billion CFU
Streptococcus thermophilus	1.5 billion CFU

Other Ingredients (Excipients)

colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
magnesium stearate
maltodextrin
potable water
potassium acetate

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary