



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	336058	ENBIOTIC
ARTG entry for	Medicine Listed	
Sponsor	Natural Bio Pty Limited	
Postal Address	PO Box 384, MONA VALE, NSW, 1660 Australia	
ARTG Start Date	8/05/2020	
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 . ENBIOTIC

Product Type	Single Medicine Product	Effective Date	12/07/2021
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Permitted Indications

Decrease/reduce/relieve bowel discomfort
Helps enhance/promote healthy digestive system function
Maintain/support healthy digestive system function
Enhance/promote healthy digestion
Maintain/support healthy digestion
Maintain/support digestion/assimilation of nutrients
Aid/assist digestion/breakdown of dietary fat
Aid/assist/helps digestion of fats/fatty acids/triglycerides/lipid
Aid/assist digestion of glucose/sugar/carbohydrates
Aid/assist/helps digestion of (state nutrient)
Maintain/support digestive system health
Helps restore good/beneficial/friendly intestinal/gut/bowel flora
Decrease/reduce/relieve abdominal bloating/distention
Decrease/reduce/relieve abdominal pain/discomfort
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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
Product presentation must not imply or refer to gastro oesophageal reflux disease.
Product presentation must not imply or refer to serious immunological diseases.
If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

Standard Indications

No Standard Indications included on Record



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Specific Indications

No Specific Indications included on Record

Warnings

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

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

Amylase	750 DU
Bifidobacterium animalis ssp lactis	1.125 billion CFU
Bifidobacterium bifidum	125 million CFU
bromelains	.2178 million PU
Lactobacillus acidophilus	5 billion CFU
Lactobacillus rhamnosus	2.5 billion CFU
lipase	525 LipU
papain	.2352 million PU
protease	3.79 Thousand HUT

Other Ingredients (Excipients)

disodium edetate
 gellan gum
 hypromellose
 magnesium stearate
 maltodextrin
 potable water
 potassium acetate
 silicon dioxide

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