Public Summary

Summary for ARTG Entry:	328697 NRGBIOTIC
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 . NRGBIOTIC

Product Type Single Medicine Product **Effective Date** 17/01/2023

Permitted Indications

Helps enhance/promote healthy muscle function
Enhance/promote energy levels
Support healthy emotional/mood balance
Maintain/support nervous system health
Aid/assist/helps synthesis of neurotransmitters
Helps reduce occurrence of symptoms of mild anxiety
Aid/assist/helps post exercise recovery

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to chronic fatigue syndrome.
Product presentation must only refer to mild anxiety.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Do not take while on warfarin therapy without medical advice.
If symptoms persist consult your healthcare practitioner (or words to that effect).

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 bifidum	**1 billion CFU**
Lactobacillus acidophilus	**2.5 billion CFU**
magnesium orotate	**400 mg**
Equivalent: magnesium	25.5 mg
Streptococcus thermophilus	**1.5 billion CFU**
ubidecarenone	**37.5 mg**

Other Ingredients (Excipients)

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