



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	387050	Immune Biotics
ARTG entry for	Medicine Listed	
Sponsor	Give Back Health Pty Ltd	
Postal Address	10/5 Canopus Street, Bridgeman Downs, QLD, 4035 Australia	
ARTG Start Date	13/04/2022	
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 . Immune Biotics

Product Type	Single Medicine Product	Effective Date	13/04/2022
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Permitted Indications

- Maintain/support general health and wellbeing
- Maintain/support healthy teeth
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Help maintain/support bone mineralisation
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Maintain/support small intestine health
- Maintain/support intestinal health
- Maintain/support healthy digestive system function
- Maintain/support digestion/assimilation of nutrients
- Maintain/support digestive system health
- Maintain/support good/beneficial/friendly bacteria adherence to intestinal mucosa
- Maintain/support intestinal good/beneficial/friendly flora
- Helps maintain/support good/beneficial/friendly gut flora during antibiotic use
- Maintain/support small intestine good/beneficial/friendly flora
- Maintain/support gastrointestinal system health
- Maintain/support healthy gastrointestinal function
- Maintain/support gastrointestinal mucosal membrane health
- Maintain/support immune system health
- Helps enhance/improve/promote immune system function
- Maintain/support immune system to fight illness
- Maintain/support healthy gastrointestinal immune function
- Maintain/support muscle health
- Maintain/support muscle function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

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Maintain/support (state vitamin/mineral/nutrient) levels in the body
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
 Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
 Maintain/support neuromuscular function
 Maintain/support nervous system health
 Helps decrease/reduce/relieve the severity of symptoms of common colds and flu
 Helps reduce occurrence of symptoms of upper respiratory tract infections in healthy individuals

Indication Requirements

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
 Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to serious immunological diseases.
 Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
 Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
 If symptoms persist consult your healthcare practitioner (or words to that effect).
 Adults only. OR Not to be used in children under two years of age without medical advice (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 lactis	1 billion CFU
colecalfiferol	.0125 mg
Lactobacillus rhamnosus	10 billion CFU

Other Ingredients (Excipients)

Acacia
 colloidal anhydrous silica
 d-alpha-tocopherol
 fractionated coconut oil
 hypromellose
 leucine

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liquid glucose
microcrystalline cellulose
purified water
silicon dioxide
sodium ascorbate

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