



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	363493	Advanced Synbiotic Powder
ARTG entry for	Medicine Listed	
Sponsor	Gutbiome Aust Pty Ltd	
Postal Address	12A Whitehall Avenue, Birkdale, QLD, 4159 Australia	
ARTG Start Date	28/04/2021	
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 . Advanced Synbiotic Powder

Product Type	Single Medicine Product	Effective Date	28/04/2021
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Permitted Indications

Maintain/support general health and wellbeing
Decrease/reduce/relieve diarrhoea in children
Helps reduce occurrence of symptoms of traveller's diarrhoea
Maintain/support healthy bowel/colon function
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
Help restore good/beneficial/friendly gut flora after antibiotic use
Helps restore good/beneficial/friendly intestinal/gut/bowel flora
Helps enhance/improve/promote/increase healthy digestive system flora/good bacteria growth
Helps enhance/improve/promote/increase intestinal good/beneficial/friendly bacteria growth
Maintain/support small intestine good/beneficial/friendly flora
Maintain/support gastrointestinal system health
Helps enhance/promote gastrointestinal system health
Maintain/support healthy gastrointestinal function
Maintain/support gastrointestinal mucosal membrane health
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support healthy gastrointestinal immune function
Helps reduce occurrence of symptoms of upper respiratory tract infections in healthy individuals

Indication Requirements



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Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Product presentation must not imply or refer to serious immunological diseases.

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).

Label statement: If symptoms persist, talk to your health professional.

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).

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).

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
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Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral

Visual Identification

Active Ingredients

Actinidia chinensis fruit Powder	185 mg/g
Bifidobacterium animalis ssp lactis	666.7 million CFU/g
Bifidobacterium bifidum	66.7 million CFU/g
Bifidobacterium breve	66.7 million CFU/g
Bifidobacterium infantis	100 million CFU/g
Bifidobacterium lactis	666.7 million CFU/g
Bifidobacterium longum	66.7 million CFU/g
Lactobacillus acidophilus	333.3 million CFU/g
Lactobacillus brevis	66.7 million CFU/g
Lactobacillus casei	300 million CFU/g
Lactobacillus delbrueckii ssp bulgaricus	66.7 million CFU/g
Lactobacillus gasseri	33.3 million CFU/g
Lactobacillus paracasei	333.3 million CFU/g
Lactobacillus plantarum	500 million CFU/g
Lactobacillus reuteri	33.3 million CFU/g
Lactobacillus rhamnosus	3.333 billion CFU/g
Lactobacillus salivarius ssp salivarius	66.7 million CFU/g
Saccharomyces cerevisiae (Bouardii)	833.3 million CFU/g
Streptococcus thermophilus	200 million CFU/g

Other Ingredients (Excipients)

- colloidal anhydrous silica
- glycine
- microcrystalline cellulose
- silicon dioxide

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