



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	363493	Advanced Synbiotic Powder
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Gutbiome Aust Pty Ltd	
<b>Postal Address</b>	12A Whitehall Avenue, Birkdale, QLD, 4159 Australia	
<b>ARTG Start Date</b>	28/04/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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 immunological diseases.

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

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: 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 forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Adults only. OR Not to be used in children under two years of age without medical advice (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).

If symptoms persist consult your healthcare practitioner (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 (Boulevardii)	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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