



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	363492	Advanced Synbiotic Capsules
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 Capsules

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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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).

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).

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 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).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

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

Other Ingredients (Excipients)

colloidal anhydrous silica
 disodium edetate
 gellan gum
 hypromellose
 magnesium stearate

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microcrystalline cellulose

potable water

potassium acetate

silicon dioxide

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