



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	358034	Children's Probiotic 15 billion
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	29/03/2021	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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 . Children's Probiotic 15 billion

Product Type	Single Medicine Product	Effective Date	29/03/2021
---------------------	-------------------------	-----------------------	------------

Permitted Indications

- Maintain/support general health and wellbeing in children
- Maintain/support digestive system health in children
- Maintain/support good/beneficial/friendly bacteria adherence to intestinal mucosa in children
- Maintain/support intestinal good/beneficial/friendly flora in children
- Helps maintain/support good/beneficial/friendly gut flora during antibiotic use in children
- Helps restore good/beneficial/friendly intestinal/gut/bowel flora in children
- Maintain/support gastrointestinal system health in children
- Maintain/support gastrointestinal mucosal membrane health in children
- Aids/assists repair of gastrointestinal/gut wall lining in children
- Maintain/support immune system health in children
- Maintain/support healthy immune system function in children

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
------------------	------------------------

Components

1 . Formulation 1

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Bifidobacterium animalis ssp lactis	.25 billion CFU/g
Bifidobacterium breve	.5 billion CFU/g
Bifidobacterium infantis	.25 billion CFU/g
Bifidobacterium lactis	.5 billion CFU/g
Bifidobacterium longum	.5 billion CFU/g
Lactobacillus acidophilus	2 billion CFU/g
Lactobacillus brevis	.25 billion CFU/g
Lactobacillus casei	.5 billion CFU/g
Lactobacillus gasseri	1 billion CFU/g
Lactobacillus paracasei	1 billion CFU/g
Lactobacillus plantarum	1 billion CFU/g
Lactobacillus reuteri	.5 billion CFU/g
Lactobacillus rhamnosus	5 billion CFU/g
Lactobacillus rhamnosus	.25 billion CFU/g
Lactobacillus rhamnosus	1 billion CFU/g
Streptococcus thermophilus	.5 billion CFU/g

Other Ingredients (Excipients)

colloidal anhydrous silica
fructooligosaccharides
inulin
maltodextrin

Public Summary

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.