



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	290547	Probiotic 55 Billion
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	22/06/2017	
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 . Probiotic 55 Billion

Product Type	Single Medicine Product	Effective Date	28/02/2022
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Permitted Indications

- Maintain/support general health and wellbeing
- Decrease/reduce/relieve constipation
- Helps reduce occurrence of constipation
- Enhance/improve/promote/increase bowel regularity
- Maintain/support bowel regularity
- Maintain/support healthy bowel/colon function
- Decrease/reduce/relieve flatulence/carminative
- Maintain/support small intestine health
- Maintain/support healthy digestive system function
- 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
- Maintain/support small intestine good/beneficial/friendly flora
- Maintain/support gastrointestinal system health
- Maintain/support healthy gastrointestinal function
- Maintain/support gastrointestinal mucosal membrane health
- Aids/assists repair of gastrointestinal/gut wall lining
- Decrease/reduce/relieve abdominal pain/discomfort
- Relieve digestive discomfort
- Decrease/reduce/relieve nausea
- Maintain/support immune system health
- Maintain/support healthy immune system function

Indication Requirements

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Label statement: Drink plenty of water (or words to that effect).

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

Label statement: Do not use when abdominal pain, nausea or vomiting are present or if you develop diarrhoea. If you are pregnant or breastfeeding - seek the advice of a healthcare professional before taking this product (or words to that effect).

Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.

Product presentation must not refer to or imply weight loss.

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

Product presentation must not imply or refer to gastro oesophageal reflux disease.

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

Dosage Form Capsule, hard
Route of Administration Oral

Visual Identification

Active Ingredients

Bifidobacterium lactis	2 billion CFU
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Lactobacillus acidophilus	.3 billion CFU
Lactobacillus gasseri	.2 billion CFU
Lactobacillus paracasei	24.9 billion CFU
Lactobacillus plantarum	15 billion CFU
Lactobacillus rhamnosus	6 billion CFU
Lactobacillus rhamnosus	5 billion CFU
Lactobacillus salivarius ssp salivarius	.3 billion CFU
Saccharomyces cerevisiae (Boulardii)	.1 billion CFU
Streptococcus thermophilus	1 billion CFU

Other Ingredients (Excipients)

colloidal anhydrous silica
 hypromellose
 magnesium stearate
 microcrystalline cellulose
 purified water
 sorbitan monostearate

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