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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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**	8/01/2020

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

Product presentation must not refer to or imply weight loss.

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.

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

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

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

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

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	**5 billion CFU**
Lactobacillus rhamnosus	**6 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

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