



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	299407	Probiotic + SB
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Herbs of Gold Pty Ltd	
<b>Postal Address</b>	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
<b>ARTG Start Date</b>	7/02/2018	
<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 . Probiotic + SB

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	18/11/2022
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### Permitted Indications

- Maintain/support general health and wellbeing
- Decrease/reduce/relieve diarrhoea
- Decrease/reduce loose stools
- Helps decrease/reduce/relieve symptoms of traveller's diarrhoea
- Helps reduce occurrence of symptoms of traveller's diarrhoea
- Maintain/support small intestine health
- Maintain/support healthy digestive system function
- Maintain/support digestive system health
- 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
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Relieve symptoms of mild upper respiratory tract infections

### Indication Requirements

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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: If symptoms persist, talk to your health professional.

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).



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**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**

<b>Bifidobacterium lactis</b>	<b>2 billion CFU</b>
<b>Lactobacillus acidophilus</b>	<b>1.5 billion CFU</b>
<b>Lactobacillus plantarum</b>	<b>1.5 billion CFU</b>
<b>Saccharomyces cerevisiae (Boulardii)</b>	<b>6 billion CFU</b>

**Other Ingredients (Excipients)**

colloidal anhydrous silica

hypromellose

magnesium stearate

microcrystalline cellulose

purified water

sorbitan monostearate

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