



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	328814	Baby Probiotic 12 Billion
<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>	20/01/2020	
<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.

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 . Baby Probiotic 12 Billion**

Product Type	Effective Date
Single Medicine Product	3/02/2020

**Permitted Indications**

- Maintain/support general health and wellbeing in healthy children under 2 years of age
- Maintain/support general health and wellbeing in infants
- Maintain/support digestive system health in healthy children under 2 years of age
- Maintain/support digestive system health in infants
- Maintain/support good/beneficial/friendly bacteria adherence to intestinal mucosa in healthy children under 2 years of age
- Maintain/support good/beneficial/friendly bacteria adherence to intestinal mucosa in infants
- Maintain/support intestinal good/beneficial/friendly flora in healthy children under 2 years of age
- Maintain/support intestinal good/beneficial/friendly flora in infants
- Helps maintain/support good/beneficial/friendly gut flora during antibiotic use in healthy children under 2 years of age
- Helps maintain/support good/beneficial/friendly gut flora during antibiotic use in infants
- Helps restore good/beneficial/friendly intestinal/gut/bowel flora in healthy children under 2 years of age
- Helps restore good/beneficial/friendly intestinal/gut/bowel flora in infants
- Maintain/support gastrointestinal system health in healthy children under 2 years of age
- Maintain/support gastrointestinal system health in infants
- Maintain/support gastrointestinal mucosal membrane health in healthy children under 2 years of age
- Maintain/support gastrointestinal mucosal membrane health in infants
- Maintain/support immune system health in infants
- Maintain/support immune system health in healthy children under 2 years of age
- Maintain/support healthy immune system function in infants

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Maintain/support healthy immune system function in healthy children under 2 years of age

**Indication Requirements**

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** Powder, oral

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Bifidobacterium animalis ssp lactis</b>	<b>.5 billion CFU/g</b>
<b>Bifidobacterium bifidum</b>	<b>.4 billion CFU/g</b>
<b>Bifidobacterium breve</b>	<b>.5 billion CFU/g</b>
<b>Bifidobacterium infantis</b>	<b>.4 billion CFU/g</b>
<b>Bifidobacterium lactis</b>	<b>.5 billion CFU/g</b>
<b>Bifidobacterium lactis</b>	<b>1 billion CFU/g</b>
<b>Bifidobacterium longum</b>	<b>.2 billion CFU/g</b>
<b>Lactobacillus paracasei</b>	<b>4 billion CFU/g</b>
<b>Lactobacillus rhamnosus</b>	<b>1 billion CFU/g</b>
<b>Lactobacillus rhamnosus</b>	<b>.5 billion CFU/g</b>
<b>Lactobacillus rhamnosus</b>	<b>3 billion CFU/g</b>

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
 fructooligosaccharides  
 maltodextrin

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