



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

## Public Summary

<b>Summary for ARTG Entry:</b>	325634	Probiotic +
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	JSHealth Vitamins Pty Ltd	
<b>Postal Address</b>	17 Kimberley Street, Vaucluse, NSW, 2030 Australia	
<b>ARTG Start Date</b>	28/10/2019	
<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.

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 +

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	16/06/2020
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### Permitted Indications

Decrease/reduce/relieve constipation  
Maintain/support bowel regularity  
Maintain/support healthy bowel/colon function  
Maintain/support intestinal health  
Maintain/support healthy digestive system function  
Maintain/support healthy digestion  
Maintain/support intestinal good/beneficial/friendly flora  
Maintain/support gastrointestinal system health  
Maintain/support healthy gastrointestinal function  
Maintain/support healthy immune system function  
Maintain/support healthy immune system function in children

### Indication Requirements

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

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

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).

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

Product presentation must not refer to or imply weight loss.

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

### Standard Indications

No Standard Indications included on Record

### Specific Indications



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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 animalis ssp lactis</b>	<b>2.5 billion CFU</b>
<b>Bifidobacterium lactis</b>	<b>1 billion CFU</b>
<b>Bifidobacterium longum</b>	<b>3 billion CFU</b>
<b>Lactobacillus casei</b>	<b>1 billion CFU</b>
<b>Lactobacillus paracasei</b>	<b>25.5 billion CFU</b>
<b>Lactobacillus plantarum</b>	<b>1 billion CFU</b>
<b>Lactobacillus rhamnosus</b>	<b>1 billion CFU</b>

**Other Ingredients (Excipients)**

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

magnesium stearate

microcrystalline cellulose

potable water

potassium acetate

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