



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

## Public Summary

<b>Summary for ARTG Entry:</b>	315959	ACTIVATED PROBIOTICS BIOME ADVANCED
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Biome Australia Limited	
<b>Postal Address</b>	L2 Professional Chambers 120 Collins Street, Melbourne, VIC, 3000 Australia	
<b>ARTG Start Date</b>	29/03/2019	
<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 . ACTIVATED PROBIOTICS BIOME ADVANCED

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	18/04/2020
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#### Permitted Indications

Enhance/improve/promote/increase bowel regularity

Enhance/promote healthy digestion

Helps maintain/support good/beneficial/friendly gut flora during antibiotic use

Help restore good/beneficial/friendly gut flora after antibiotic use

#### Indication Requirements

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

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

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 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

No Specific Indications included on Record

#### Warnings

No Warnings included on Record

#### Additional Product information

#### Container information



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Type	Material	Life Time	Temperature	Closure	Conditions
Carton	Not recorded	Not recorded	Not recorded	Neither child resistant closure nor restricted flow insert	Not recorded

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Capsule, hard
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>Bifidobacterium animalis ssp lactis</b>	<b>10 billion CFU</b>
<b>Lactobacillus acidophilus</b>	<b>5 billion CFU</b>
<b>Lactobacillus paracasei</b>	<b>.5 billion CFU</b>
<b>Lactobacillus plantarum</b>	<b>9.5 billion CFU</b>
<b>Lactobacillus rhamnosus</b>	<b>5 billion CFU</b>

**Other Ingredients (Excipients)**

glyceryl palmito-stearate  
hypromellose  
maltodextrin  
silicon dioxide  
titanium dioxide

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