



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	355438	ACTIVATED PROBIOTICS BIOME BREATHE
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Biome Australia Limited	
<b>Postal Address</b>	16 Dover Street, Cremorne, VIC, 3121 Australia	
<b>ARTG Start Date</b>	23/02/2021	
<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 . ACTIVATED PROBIOTICS BIOME BREATHE**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	23/02/2021
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**Permitted Indications**

Maintain/support healthy immune system function  
Helps stimulate a healthy immune system response in children over 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**

**Container information**

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

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Powder, oral
<b>Route of Administration</b>	Oral

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**Visual Identification**

**Active Ingredients**

<b>Bifidobacterium breve</b>	<b>.5 billion organisms/g</b>
<b>Lactobacillus salivarius ssp salivarius</b>	<b>.5 billion organisms/g</b>

**Other Ingredients (Excipients)**

maltodextrin  
silicon dioxide  
sorbitol  
Vanilla Powder  
xylitol

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