



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	315959	ACTIVATED PROBIOTICS BIOME ADVANCED
ARTG entry for	Medicine Listed	
Sponsor	Biome Australia Limited	
Postal Address	192/194 Johnston Street, Collingwood, VIC, 3066 Australia	
ARTG Start Date	29/03/2019	
Product Category	Medicine	
Status	Active	
Approval Area	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 ADVANCED

Product Type	Single Medicine Product	Effective Date	19/08/2025
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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

Product presentation must not refer to or imply weight loss.

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).

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

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



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Pack Size/Poison information	
Pack Size	Poison Schedule
Components	
1 . Formulation 1	
Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	
Active Ingredients	
Bifidobacterium animalis ssp lactis	10 billion CFU
Lactobacillus acidophilus	5 billion CFU
Lactobacillus paracasei	.5 billion CFU
Lactobacillus plantarum	9.5 billion CFU
Lactobacillus rhamnosus	5 billion CFU
Other Ingredients (Excipients)	
glyceryl palmito-stearate	
hypromellose	
maltodextrin	
silicon dioxide	

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