



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		316346	ACTIVATED PROBIOTICS BIOME RECOVERY PROBIOTIC
ARTG entry for	Medicine Listed		
Sponsor	Biome Australia Limited		
Postal Address	192/194 Johnston Street, Collingwood, VIC, 3066 Australia		
ARTG Start Date	10/04/2019		
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 RECOVERY PROBIOTIC

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

Permitted Indications

Maintain/support healthy muscle contraction function

Helps enhance/promote healthy muscle function

Reduce/decrease mild muscle inflammation

Aid/assist/helps post exercise recovery

Helps enhance/improve muscle recovery time

Indication Requirements

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

Pack Size/Poison information

Pack Size	Poison Schedule
------------------	------------------------

Components

1 . Formulation 1



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Bifidobacterium breve 5 billion CFU

Streptococcus thermophilus 5 billion CFU

Other Ingredients (Excipients)

glyceryl palmito-stearate

hypromellose

maltodextrin

titanium dioxide

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary