



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	317898	ACTIVATED PROBIOTICS BIOME DAILY KIDS
ARTG entry for	Medicine Listed	
Sponsor	Biome Australia Limited	
Postal Address	16 Dover Street, Cremorne, VIC, 3121 Australia	
ARTG Start Date	24/05/2019	
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.

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 DAILY KIDS

Product Type	Single Medicine Product	Effective Date	30/04/2020
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Permitted Indications

Help reduce occurrence of symptoms of medically diagnosed Irritable Bowel Syndrome

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

Helps enhance/improve/promote immune system function

Helps reduce occurrence of common colds

Decrease/reduce/relieve common cold duration

Indication Requirements

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

Product presentation must only refer to medically diagnosed IBS.

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

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

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



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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

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

Bifidobacterium animalis ssp lactis	1.25 billion CFU/g
Bifidobacterium breve	1.25 billion CFU/g
Lactobacillus casei	.625 billion CFU/g
Lactobacillus plantarum	1.9 billion CFU/g
Lactobacillus rhamnosus	1.25 billion CFU/g

Other Ingredients (Excipients)

glyceryl palmito-stearate

maltodextrin

silicon dioxide

sorbitol

Vanilla Powder

xylitol

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