Public Summary

Summary for ARTG Entry:	315375 ACTIVATED PROBIOTICS BIOME IBS
ARTG entry for	Medicine Listed
Sponsor	Biome Australia Limited
Postal Address	192/194 Johnston Street, Collingwood, VIC, 3066 Australia
ARTG Start Date	13/03/2019
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 IBS

Product Type Single Medicine Product **Effective Date** 19/10/2023

Permitted Indications

Enhance/improve/promote/increase bowel regularity

Relief of symptoms of medically diagnosed Irritable Bowel Syndrome in adults

Decrease/reduce/relieve abdominal bloating/distention in adults

Indication Requirements

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

Product presentation must only refer to medically diagnosed IBS.

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

Product presentation must not refer to or imply weight loss.

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

Label statement: If symptoms persist or worsen talk to your medical practitioner.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Do not use if pregnant or likely to become pregnant (or words to that effect)

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Not recorded	Not recorded	Not recorded	Neither child resistant	Not recorded

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closure nor restricted
flow insert

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 breve	**3 billion CFU**
Lactobacillus plantarum	**10 billion CFU**
Lactobacillus rhamnosus	**10 billion CFU**

Other Ingredients (Excipients)

hypromellose
maltodextrin
silicon dioxide

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