



Australian Government

Department of Health, Disability and Ageing  
Therapeutic Goods Administration

Public Summary

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

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 19/08/2025 |
|---------------------|-------------------------|-----------------------|------------|

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

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

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

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).

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

Product presentation must not refer to or imply weight loss.

Product presentation must only refer to medically diagnosed IBS.

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

|              |                 |                  |                    |                         |                   |
|--------------|-----------------|------------------|--------------------|-------------------------|-------------------|
| <b>Type</b>  | <b>Material</b> | <b>Life Time</b> | <b>Temperature</b> | <b>Closure</b>          | <b>Conditions</b> |
| 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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