



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 364311 BIOME HER

ARTG entry for Medicine Listed
Sponsor Biome Australia Limited
Postal Address 16 Dover Street, Cremorne, VIC, 3121
 Australia
ARTG Start Date 4/05/2021
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 . BIOME HER

Product Type	Single Medicine Product	Effective Date	4/05/2021
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Permitted Indications

Maintain/support vaginal healthy flora/microflora

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

'Contains gluten (or words to that effect)'

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
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Components

1 . Formulation 1

Dosage Form Capsule, hard
Route of Administration Oral

Visual Identification

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Active Ingredients

Lactobacillus acidophilus	1 billion organisms
Lactobacillus crispatus	1 billion organisms
Lactobacillus fermentum	1 billion organisms

Other Ingredients (Excipients)

hypromellose
maltodextrin
silicon dioxide

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