



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	364311	BIOME HER
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Biome Australia Limited	
<b>Postal Address</b>	192/194 Johnston Street, Collingwood, VIC, 3066 Australia	
<b>ARTG Start Date</b>	4/05/2021	
<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 . BIOME HER**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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**

<b>Pack Size</b>	<b>Poison Schedule</b>
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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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