



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	369999	Eagle FloraBalance
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	22/06/2021	
<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 . Eagle FloraBalance

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	22/06/2021
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### Permitted Indications

- Maintain/support general health and wellbeing
- Relief of symptoms of medically diagnosed Irritable Bowel Syndrome
  - Linked indication - Decrease/reduce/relieve flatulence/carminative
  - Linked indication - Decrease/reduce/relieve excess intestinal gas
  - Linked indication - Decrease/reduce/relieve abdominal bloating/distention
  - Linked indication - Decrease/reduce/relieve abdominal pain/discomfort
- Maintain/support intestinal good/beneficial/friendly flora in adults
- Maintain/support intestinal good/beneficial/friendly flora in children over 2 years of age
- Maintain/support intestinal good/beneficial/friendly flora
- Maintain/support small intestine good/beneficial/friendly flora in adults
- Maintain/support small intestine good/beneficial/friendly flora in children over 2 years of age
- Maintain/support small intestine good/beneficial/friendly flora
- Maintain/support gastrointestinal system health in adults
- Maintain/support gastrointestinal system health in children over 2 years of age
- Maintain/support gastrointestinal system health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support vaginal healthy flora/microflora

### Indication Requirements

- Product presentation must not imply or refer to gastro oesophageal reflux disease.  
Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to serious immunological diseases.  
Product presentation must only refer to medically diagnosed IBS.  
Label statement: If symptoms persist or worsen talk to your medical practitioner.

### Standard Indications

No Standard Indications included on Record

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**Specific Indications**

No Specific Indications included on Record

**Warnings**

If symptoms persist consult your healthcare practitioner (or words to that effect).  
If symptoms persist, seek the advice of a healthcare professional.  
For practitioner dispensing only.

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Powder, oral

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Bifidobacterium breve</b>	<b>600 million CFU/g</b>
<b>Bifidobacterium infantis</b>	<b>600 million CFU/g</b>
<b>Bifidobacterium longum</b>	<b>600 million CFU/g</b>
<b>Lactobacillus acidophilus</b>	<b>1.1 billion CFU/g</b>
<b>Lactobacillus casei</b>	<b>800 million CFU/g</b>
<b>Lactobacillus delbrueckii ssp bulgaricus</b>	<b>100 million CFU/g</b>
<b>Lactobacillus helveticus</b>	<b>1 billion CFU/g</b>
<b>Lactobacillus plantarum</b>	<b>800 million CFU/g</b>
<b>Lactobacillus rhamnosus</b>	<b>8 billion CFU/g</b>
<b>Lactobacillus rhamnosus</b>	<b>6 billion CFU/g</b>
<b>Streptococcus thermophilus</b>	<b>400 million CFU/g</b>

**Other Ingredients (Excipients)**

ascorbic acid  
colloidal anhydrous silica  
inulin  
magnesium stearate  
maltodextrin  
microcrystalline cellulose

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