



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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

Product Type	Single Medicine Product	Effective Date	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 children over 2 years of age
Maintain/support intestinal good/beneficial/friendly flora
Maintain/support intestinal good/beneficial/friendly flora in adults
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 children over 2 years of age
Maintain/support gastrointestinal system health in adults
Maintain/support gastrointestinal system health
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support vaginal healthy flora/microflora

Indication Requirements

Label statement: If symptoms persist or worsen talk to your medical practitioner.
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, talk to your health professional.
Product presentation must not imply or refer to gastro oesophageal reflux disease.

Standard Indications

No Standard Indications included on Record



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Specific Indications

No Specific Indications included on Record

Warnings

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

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

Other Ingredients (Excipients)

ascorbic acid
colloidal anhydrous silica
inulin
magnesium stearate
maltodextrin
microcrystalline cellulose

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