Public Summary

Summary for ARTG Entry:	220743	Eagle CytoPro Balance Probiotic Powder

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	6/03/2014
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 CytoPro Balance Probiotic Powder

Product Type	Single Medicine Product	**Effective Date**	12/08/2019

Permitted Indications

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

Indication Requirements

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

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

Product presentation must only refer to medically diagnosed IBS.

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

Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

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	**6 billion CFU/g**
Lactobacillus rhamnosus	**8 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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