



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	272899	BioOne Lactobacillus Rhamnosus
ARTG entry for	Medicine Listed	
Sponsor	Spectrumceuticals Pty Ltd	
Postal Address	10/5 Narabang Way, BELROSE, NSW, 2085 Australia	
ARTG Start Date	15/03/2016	
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 . BioOne Lactobacillus Rhamnosus

Product Type	Single Medicine Product	Effective Date	23/10/2018
---------------------	-------------------------	-----------------------	------------

Permitted Indications

- Maintain/support general health and wellbeing
- Decrease/reduce/relieve diarrhoea in children
- Relief of symptoms of medically diagnosed Irritable Bowel Syndrome in children over 5 years of age
- Maintain/support intestinal health
- Maintain/support intestinal good/beneficial/friendly flora
- Maintain/support small intestine good/beneficial/friendly flora
- Maintain/support gastrointestinal system health
- Maintain/support gastrointestinal mucosal membrane health
- Decrease/reduce/relieve abdominal pain/discomfort in children over 5 years of age
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy gastrointestinal immune function
- Helps reduce occurrence of symptoms of eczema/dermatitis in children
- Helps reduce occurrence of symptoms of eczema/dermatitis in healthy infants

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



Australian Government
Department of Health
Therapeutic Goods Administration

Product presentation must only refer to medically diagnosed IBS.

Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Lactobacillus rhamnosus

20 billion CFU

Other Ingredients (Excipients)

colloidal anhydrous silica

gellan gum

hypromellose

microcrystalline cellulose

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary