Australian Government

Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	336202 L. Rhamnosus
ARTG entry for	Medicine Listed
Sponsor	Spectrumceuticals Pty Ltd
Postal Address	10/5 Narabang Way, BELROSE, NSW, 2085 Australia
ARTG Start Date	12/05/2020
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.

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 . L. Rhamnosus

Product Type	Single Medicine Product	**Effective Date**	12/05/2020

Permitted Indications

Maintain/support general health and wellbeing
Decrease/reduce/relieve diarrhoea in children
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
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support healthy gastrointestinal immune function

Indication Requirements

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

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**
- **disodium edetate**
- **gellan gum**
- **hypromellose**
- **magnesium stearate**
- **microcrystalline cellulose**
- **potable water**
- **potassium acetate**