Public Summary

Summary for ARTG Entry:	239102 ORSBiotic
ARTG entry for	Medicine Listed
Sponsor	Medlab Pty Ltd
Postal Address	PO Box 6452, ALEXANDRIA, NSW, 2015 Australia
ARTG Start Date	27/05/2015
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 . ORSBiotic

Product Type Single Medicine Product **Effective Date** 24/08/2020

Permitted Indications

Decrease/reduce/relieve symptoms of dehydration

Maintain/support body electrolyte balance

Helps restore body electrolyte balance

Decrease/reduce/relieve diarrhoea

Helps reduce occurrence of diarrhoea

Maintain/support gastrointestinal system health

Maintain/support immune system health

Indication Requirements

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).

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

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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 3-6 years or 48 hours in adults and children over 6 years, seek medical advice (or words to that effect).

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

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

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WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Powder
Route of Administration	Oral
Visual Identification	

Active Ingredients

Bifidobacterium breve	**.4 billion CFU/g**
citric acid	**178.1 mg/g**
glucose	**507.82 mg/g**
Lactobacillus gasseri	**.4 billion CFU/g**
Lactobacillus plantarum	**.4 billion CFU/g**
potassium citrate	**89.81 mg/g**
Equivalent: potassium	32.52 mg/g
Equivalent: citrate	52.36 mg/g
Saccharomyces cerevisiae (Boulardii)	**.4 billion CFU/g**
sodium chloride	**106.65 mg/g**
Equivalent: sodium	41.94 mg/g
Equivalent: chloride	64.7 mg/g
zinc gluconate	**8.96 mg/g**
Equivalent: zinc	1.28 mg/g

Other Ingredients (Excipients)

Carrot
colloidal anhydrous silica
Flavour
Stevia rebaudiana
thaumatin

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