



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	359995	ORSBiotic
ARTG entry for	Medicine Listed	
Sponsor	Natural Bio Pty Limited	
Postal Address	PO Box 384, MONA VALE, NSW, 1660 Australia	
ARTG Start Date	7/04/2021	
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 . ORSBiotic

Product Type	Single Medicine Product	Effective Date	9/12/2022
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Permitted Indications

Decrease/reduce/relieve symptoms of dehydration
Maintain/support body electrolyte balance
Helps restore body electrolyte balance
Decrease/reduce/relieve diarrhoea in children
Helps reduce occurrence of diarrhoea in children
Maintain/support gastrointestinal system health
Maintain/support immune system health

Indication Requirements

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

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).

If symptoms persist consult your healthcare practitioner (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 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).

Additional Product information

Public Summary



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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		.333 billion CFU/g
citric acid		149.7 mg/g
glucose		496.167 mg/g
Lactobacillus gasseri		.333 billion CFU/g
Lactobacillus plantarum		.333 billion CFU/g
potassium citrate		75.492 mg/g
Equivalent: citrate		43.975 mg/g
Equivalent: potassium		27.328 mg/g
Saccharomyces cerevisiae (Boulardii)		.333 billion CFU/g
sodium chloride		89.642 mg/g
Equivalent: sodium		35.229 mg/g
Equivalent: chloride		54.377 mg/g
zinc gluconate		1.167 mg/g
Equivalent: zinc		.167 mg/g
Other Ingredients (Excipients)		
colloidal anhydrous silica		
Flavour		
inulin		
sorbitan monostearate		
Stevia rebaudiana		
thaumatin		

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