



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	359995	ORSBiotic
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Natural Bio Pty Limited	
<b>Postal Address</b>	PO Box 384, MONA VALE, NSW, 1660 Australia	
<b>ARTG Start Date</b>	7/04/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	1/07/2021
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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

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).

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

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 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].

#### Additional Product information

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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**

<b>Bifidobacterium breve</b>	<b>.333 billion CFU/g</b>
<b>citric acid</b>	<b>149.7 mg/g</b>
<b>glucose</b>	<b>496.167 mg/g</b>
<b>Lactobacillus gasseri</b>	<b>.333 billion CFU/g</b>
<b>Lactobacillus plantarum</b>	<b>.333 billion CFU/g</b>
<b>potassium citrate</b>	<b>75.492 mg/g</b>
Equivalent: citrate	43.975 mg/g
Equivalent: potassium	27.328 mg/g
<b>Saccharomyces cerevisiae (Boulardii)</b>	<b>.333 billion CFU/g</b>
<b>sodium chloride</b>	<b>89.642 mg/g</b>
Equivalent: sodium	35.229 mg/g
Equivalent: chloride	54.377 mg/g
<b>zinc gluconate</b>	<b>1.167 mg/g</b>
Equivalent: zinc	.167 mg/g

**Other Ingredients (Excipients)**

**colloidal anhydrous silica**

**Flavour**

**inulin**

**sorbitan monostearate**

**Stevia rebaudiana**

**thaumatin**

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