



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	353394	Biotic Jnr.
<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>	21/01/2021	
<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 . Biotic Jnr.

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	21/01/2021
---------------------	-------------------------	-----------------------	------------

#### Permitted Indications

- Maintain/support healthy growth and development in infants
- Maintain/support general health and wellbeing in infants
- Decrease/reduce/relieve diarrhoea in infants
- Decrease/reduce loose stools in infants
- Maintain/support intestinal good/beneficial/friendly flora in infants
- Maintain/support gastrointestinal system health in infants
- Helps decrease/reduce/relieve mild gastrointestinal tract inflammation in infants
- Maintain/support healthy immune system function in infants
- Helps reduce occurrence of symptoms of eczema/dermatitis in infants

#### 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

- If symptoms persist consult your healthcare practitioner (or words to that effect).
- Contains milk/milk products.
- 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



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

**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**

<b>Bifidobacterium infantis</b>	<b>3 billion CFU/g</b>
<b>Bifidobacterium lactis</b>	<b>1 billion CFU/g</b>
<b>Bifidobacterium longum</b>	<b>1 billion CFU/g</b>
<b>bovine lactoferrin</b>	<b>100 mg/g</b>
<b>Lactobacillus rhamnosus</b>	<b>6 billion CFU/g</b>
<b>Saccharomyces cerevisiae (Boulardii)</b>	<b>2.5 billion CFU/g</b>

**Other Ingredients (Excipients)**

**inulin**

**sorbitan monostearate**

© 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