



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	353394	Biotic Jnr.
ARTG entry for	Medicine Listed	
Sponsor	Medlab Pty Ltd	
Postal Address	PO Box 6452, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	21/01/2021	
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 . Biotic Jnr.

Product Type	Single Medicine Product	Effective Date	21/01/2021
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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: 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.

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



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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 infantis				3 billion CFU/g	
Bifidobacterium lactis				1 billion CFU/g	
Bifidobacterium longum				1 billion CFU/g	
bovine lactoferrin				100 mg/g	
Lactobacillus rhamnosus				6 billion CFU/g	
Saccharomyces cerevisiae (Boulardii)				2.5 billion CFU/g	
Other Ingredients (Excipients)					
inulin					
sorbitan monostearate					

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