



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	380458	AllerG Biotic
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	9/12/2021	
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 . AllerG Biotic

Product Type	Single Medicine Product	Effective Date	9/06/2022
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Permitted Indications

- Maintain/support intestinal good/beneficial/friendly flora in adolescents
- Maintain/support intestinal good/beneficial/friendly flora
- Decrease/reduce/relieve symptoms of hayfever in adolescents
 - Linked indication - Helps enhance/promote general health and wellbeing
 - Linked indication - Maintain/support general health and wellbeing
- Decrease/reduce/relieve symptoms of hayfever
- Helps decrease/reduce/relieve symptoms of mild allergies
 - Linked indication - Relieve eye discomfort
 - Linked indication - Relieve itchy eyes
 - Linked indication - Relieve eye soreness
 - Linked indication - Decrease/reduce/relieve watery eyes/excessive lacrimation
- Helps decrease/reduce/relieve symptoms of mild allergies in adolescents
 - Linked indication - Relieve eye discomfort
 - Linked indication - Relieve itchy eyes
 - Linked indication - Relieve eye soreness
 - Linked indication - Decrease/reduce/relieve watery eyes/excessive lacrimation
- Helps decrease/reduce/relieve symptoms of mild allergies
 - Linked indication - Helps enhance/improve/promote immune system function
 - Linked indication - Anti-inflammatory/relieve inflammation
- Helps decrease/reduce/relieve symptoms of mild allergies in children
- Decrease/reduce/relieve symptoms of allergic rhinitis in adolescents
- Decrease/reduce/relieve symptoms of allergic rhinitis
- Helps decrease/reduce/relieve symptoms of seasonal allergies
- Helps decrease/reduce/relieve symptoms of seasonal allergies in adolescents
- Maintain/support immune system health in adolescents
- Maintain/support immune system health in children
- Maintain/support immune system health
- Maintain/support healthy immune system function in adolescents
- Maintain/support healthy immune system function
- Maintain/support healthy immune system function in children

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Helps stimulate a healthy immune system response in children

Decrease/reduce/relieve skin irritation

Maintain/support skin health

Indication Requirements

Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.

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

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Bifidobacterium breve	1 billion CFU
Bifidobacterium longum	3 billion CFU
Lactobacillus fermentum	2 billion CFU
Lactobacillus paracasei	5 billion CFU
Lactobacillus rhamnosus	20 billion CFU

Other Ingredients (Excipients)

- colloidal anhydrous silica
- hypromellose
- magnesium stearate
- maize starch
- maltodextrin
- microcrystalline cellulose
- potable water
- tapioca starch
- tricalcium phosphate

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