



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

## Public Summary

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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 itchy eyes

Linked indication - Relieve eye soreness

Linked indication - Decrease/reduce/relieve watery eyes/excessive lacrimation

Linked indication - Relieve eye discomfort

Helps decrease/reduce/relieve symptoms of mild allergies

Helps decrease/reduce/relieve symptoms of mild allergies in adolescents

Linked indication - Anti-inflammatory/relieve inflammation

Linked indication - Helps enhance/improve/promote immune system function

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

Public Summary

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