



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

## Public Summary

<b>Summary for ARTG Entry:</b>	293588	Ultra Pure GG
<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>	6/09/2017	
<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 . Ultra Pure GG

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	4/03/2021
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#### Permitted Indications

Maintain/support general health and wellbeing  
Relief of symptoms of medically diagnosed Irritable Bowel Syndrome in children  
Help reduce occurrence of symptoms of medically diagnosed Irritable Bowel Syndrome in children  
Maintain/support digestion/assimilation of nutrients  
Maintain/support intestinal good/beneficial/friendly flora in children  
Maintain/support gastrointestinal system health  
Maintain/support healthy gastrointestinal function  
Maintain/support gastrointestinal mucosal membrane health  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support healthy immune system function in healthy infants  
Maintain/support healthy immune system function in children  
Maintain/support immune system to fight illness  
Maintain/support healthy gastrointestinal immune function

#### Indication Requirements

Label statement: If symptoms persist or worsen talk to your medical practitioner.  
Product presentation must not imply or refer to serious immunological diseases.  
  
Product presentation must only refer to medically diagnosed IBS.  
Label statement: If symptoms persist, worsen or episodes become more frequent talk to your medical practitioner.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

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If symptoms persist consult your healthcare practitioner (or words to that effect).

**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**

**Lactobacillus rhamnosus**

**10 billion CFU**

**Other Ingredients (Excipients)**

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

microcrystalline cellulose

potable water

potassium acetate

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