



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

## Public Summary

<b>Summary for ARTG Entry:</b>	374840	Gut-R
<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>	17/09/2021	
<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 . Gut-R

Product Type	Single Medicine Product	Effective Date	6/04/2022
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### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support healthy eye function
- Maintain/support eye health
- Aids/assists eye adaption to variations in light intensity/night vision
- Helps maintain/support healthy vision development
- Maintain/support healthy eyesight/vision
- Helps maintain/support healthy acid/alkali balance in the body
- Maintain/support healthy growth and development
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Maintain/support healthy teeth
- Anti-inflammatory/relieve inflammation in healthy individuals
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Decrease/reduce/relieve mild joint pain/soreness
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood capillary health
- Maintain/support smell sensation
- Maintain/support taste sensation
- Maintain/support healthy digestive system function
- Maintain/support healthy digestion
- Maintain/support healthy mucous linings of the digestive system
- Maintain/support digestive system health
- Maintain/support gastrointestinal system health
- Maintain/support healthy gastrointestinal function

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Maintain/support gastrointestinal mucosal membrane health  
Aids/assists repair of gastrointestinal/gut wall lining  
Helps maintain/support bile secretion/flow  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support immune system to fight illness  
Maintain/support healthy gastrointestinal immune function  
Maintain/support muscle health  
Maintain/support muscle function  
Aid/assist/helps protein synthesis in the body  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Maintain/support neuromuscular function  
Maintain/support nervous system health  
Maintain/support nervous system function  
Maintain/support female reproductive system health  
Maintain/support/regulate healthy menstrual cycle  
Maintain/support reproductive system health  
Maintain/support healthy reproductive hormones  
Maintain/support sperm production  
Maintain/support healthy mucous membranes/mucous tissue of the respiratory tract  
Maintain/support skin health  
Maintain/support skin integrity/structure  
Maintain/support wound healing in healthy individuals  
Maintain/support skin repair/healing/regeneration in healthy individuals

**Indication Requirements**

Product presentation must only refer to mild joint symptoms.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to infertility.

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to hormone imbalances.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.  
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Product presentation must not imply or refer to neurological conditions or developmental delays.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.



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**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Powder, oral

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>colecalfiferol</b>	<b>.0035 mg/g</b>
<b>Curcuma longa rhizome Extract dry concentrate standardised</b>	<b>35.7312 mg/g</b>
Equivalent: Curcuma longa (Dry)	1.1166 g/g
<b>glutamine</b>	<b>714.29 mg/g</b>
<b>polaprezinc</b>	<b>11.295 mg/g</b>
Equivalent: zinc	2.43 mg/g
<b>quercetin dihydrate</b>	<b>35.72 mg/g</b>
<b>retinol acetate</b>	<b>.1265 mg/g</b>
Equivalent: vitamin A	.1072 mg/g

**Other Ingredients (Excipients)**

**Acacia**

**colloidal anhydrous silica**

**d-alpha-tocopherol**

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**Flavour**

**fractionated coconut oil**

**glycine**

**liquid glucose**

**maize starch**

**malic acid**

**silicon dioxide**

**sodium ascorbate**

**spray-dried glucose syrup**

**Stevia rebaudiana**

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