



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	374840	Gut-R
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	17/09/2021	
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 . Gut-R

Product Type	Single Medicine Product	Effective Date	6/04/2022
---------------------	-------------------------	-----------------------	-----------

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

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

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 neurological conditions or developmental delays.

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.

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.



Australian Government
Department of Health
Therapeutic Goods Administration

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

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

Other Ingredients (Excipients)

Acacia

colloidal anhydrous silica

d-alpha-tocopherol

dl-alpha-tocopherol

Flavour

fractionated coconut oil

glycine

liquid glucose

maize starch

malic acid

silicon dioxide

sodium ascorbate

spray-dried glucose syrup

Stevia rebaudiana

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary