



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	321711	Gut Mx
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	13/08/2019	
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 Mx

Product Type	Single Medicine Product	Effective Date	1/04/2021
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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 healthy eyesight/vision
Maintain/support healthy growth and development
Maintain/support general health and wellbeing
Maintain/support smell sensation
Maintain/support taste sensation
Maintain/support healthy mucous linings of the digestive system
Maintain/support good/beneficial/friendly bacteria adherence to intestinal mucosa
Maintain/support gastrointestinal system health
Maintain/support gastrointestinal system health when travelling
Maintain/support healthy gastrointestinal function when travelling
Maintain/support healthy gastrointestinal function
Maintain/support gastrointestinal mucosal membrane health
Aids/assists repair of gastrointestinal/gut wall lining
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support healthy immune system function in healthy infants
Maintain/support healthy gastrointestinal immune function
Aid/assist/helps protein synthesis in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support female reproductive system health



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Maintain/support/regulate healthy menstrual cycle
 Maintain/support reproductive system health
 Maintain/support healthy reproductive hormones
 Maintain/support sperm production
 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 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.
 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).
 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.
 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

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.
 WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).
 If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

polaprezinc	39.5 mg
Equivalent: zinc	8.5 mg
Saccharomyces cerevisiae (Boulardii)	5 billion CFU

Other Ingredients (Excipients)

colloidal anhydrous silica
 disodium edetate
 gellan gum
 hypromellose
 microcrystalline cellulose
 potable water
 potassium acetate

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