



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	311634	MagGI Restore
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	16/11/2018	
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 . MagGI Restore

Product Type	Single Medicine Product	Effective Date	18/02/2021
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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 collagen formation
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
Maintain/support healthy growth and development
Maintain/support body mucous membrane health
Maintain/support general health and wellbeing
Maintain/support hair growth
Maintain/support hair health
Maintain/support healthy teeth
Maintain/support nail health/strength/thickness
Maintain/support connective tissue health
Aid/assist/helps connective tissue production/formation
Maintain/support bone health
Aids/assists healthy bone development/growth/building
Help maintain/support bone mineralisation
Aid/assist healthy red blood cell production
Maintain/support red blood cell health
Maintain/support blood health
Helps maintain/support haemoglobin formation/synthesis
Maintain/support cardiovascular system health
Helps maintain/support healthy heart function
Maintain/support healthy cardiovascular system function

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Maintain/support blood capillary health
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Maintain/support thyroid gland health
Aid/assist thyroid hormone production
Maintain/support smell sensation
Maintain/support taste sensation
Maintain/support small intestine health
Maintain/support intestinal health
Maintain/support healthy small intestine function
Maintain/support healthy digestive system function
Maintain/support healthy digestion
Maintain/support healthy mucous linings of the digestive system
Maintain/support digestion/assimilation of nutrients
Maintain/support digestive system health
Maintain/support gastrointestinal system health
Maintain/support healthy gastrointestinal function
Maintain/support gastrointestinal mucosal membrane health
Aids/assists repair of gastrointestinal/gut wall lining
Maintain/support bile production
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support healthy muscle contraction function
Maintain/support muscle health
Maintain/support muscle function
Maintain/support healthy neuromuscular system/function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
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 maintain/support cellular uptake of (state vitamin/mineral/nutrient)
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy individuals
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Support healthy stress response in the body
Maintain/support nerve conduction
Maintain/support neuromuscular function
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support female reproductive system health
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

Indication Requirements

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

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

Product presentation must not imply or refer to any thyroid related diseases.

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.



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Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
 Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
 Product presentation must not imply or refer to hormone imbalances.
 Product presentation must not imply or refer to serious immunological diseases.
 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 circulatory disorders/diseases/conditions e.g. thrombosis.
 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 can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
 If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.
 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.
 The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.
 This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.
 If symptoms persist, seek the advice of a healthcare professional.
 WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral

Visual Identification

Active Ingredients

alpha lipoic acid	2.5 mg/g
Biotin	37.5 microgram/g
calcium ascorbate dihydrate	15.13 mg/g
Equivalent: ascorbic acid	12.5 mg/g
calcium folinate	54 microgram/g
Equivalent: folic acid	50 microgram/g
calcium pantothenate	20.47 mg/g
Equivalent: pantothenic acid	18.75 mg/g
choline bitartrate	18.75 mg/g
chromium nicotinate	50.3 microgram/g
Equivalent: chromium	6.25 microgram/g
colecalfiferol	.0031 mg/g
glutamine	250 mg/g
hesperidin	3.13 mg/g
inositol	3.13 mg/g
magnesium citrate	239.2 mg/g
Equivalent: magnesium	38.75 mg/g

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manganese amino acid chelate	1.25 mg/g
Equivalent: manganese	125 microgram/g
mecobalamin (co-methylcobalamin)	50 microgram/g
menaquinone 7	2.5 microgram/g
molybdenum trioxide	9.38 microgram/g
Equivalent: molybdenum	6.3 microgram/g
nicotinamide	12.5 mg/g
nicotinic acid	.63 mg/g
palm tocotrienols complex	.6246 mg/g
phytomenadione	8.75 microgram/g
potassium iodide	24.53 microgram/g
Equivalent: iodine	18.75 microgram/g
pyridoxal 5-phosphate monohydrate	2.01 mg/g
Equivalent: pyridoxine	1.28 mg/g
pyridoxine hydrochloride	3.75 mg/g
Equivalent: pyridoxine	3.09 mg/g
retinol palmitate	171.75 microgram/g
Equivalent: vitamin A	93.75 RE/g
riboflavin sodium phosphate	1.25 mg/g
Equivalent: riboflavin	.98 mg/g
rutoside	3.13 mg/g
selenomethionine	18.8 microgram/g
Equivalent: selenium	7.5 microgram/g
taurine	187.5 mg/g
thiamine nitrate	6.25 mg/g
Equivalent: thiamine	5.07 mg/g
zinc citrate dihydrate	5.84 mg/g
Equivalent: zinc	1.88 mg/g

Other Ingredients (Excipients)

Acacia
butylated hydroxytoluene
colloidal anhydrous silica
d-alpha-tocopherol
dl-alpha-tocopherol
Flavour
fractionated coconut oil
glycine
liquid glucose
maize starch
malic acid
maltodextrin
Palm Fruit Oil
silicon dioxide
sodium ascorbate
starch sodium octenyl succinate
Stevia rebaudiana
sucrose

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