Australian Government

Department of Health, Disability and Ageing

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** 27/06/2025

Permitted Indications

Maintain/support general health and wellbeing

Maintain/support small intestine health

Maintain/support intestinal health

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

Maintain/support gastrointestinal mucosal membrane health

Aids/assists repair of gastrointestinal/gut wall lining

Maintain/support healthy neuromuscular system/function

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Maintain/support (state vitamin/mineral) within normal range

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

Indication Requirements

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 serious musculoskeletal or neurological conditions.

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

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

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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. IContains vitamin B6I.

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.

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

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.

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage FormPowder, oralRoute of AdministrationOral

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: folinic 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 colecalciferol .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

manganese amino acid chelate 1.25 mg/g Equivalent: manganese 125 microgram/g mecobalamin 50 microgram/g menaguinone 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/gphytomenadione8.75 microgram/gpotassium iodide24.53 microgram/g

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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 trihydrate 3.41 mg/g

selenomethionine18.8 microgram/gEquivalent: selenium7.5 microgram/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

taurine

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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187.5 mg/g