



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	229301	BioActivated Magnesium
ARTG entry for	Medicine Listed	
Sponsor	Biomedica Nutraceuticals Pty Ltd	
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	14/10/2014	
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 . BioActivated Magnesium

Product Type	Single Medicine Product	Effective Date	19/11/2020
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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 energy levels
Maintain/support general health and wellbeing
Maintain/support bone health
Aids/assists healthy bone development/growth/building
Maintain/support cardiovascular system health
Maintain/support heart health
Maintain/support immune system health
Maintain/support healthy immune system function
Antispasmodic/spasmolytic
Maintain/support healthy muscle contraction function
Maintain/support muscle health
Maintain/support muscle relaxation
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral) within normal range
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support healthy sleeping patterns

Indication Requirements

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

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

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.

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).

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 immunological diseases.

Product presentation must not imply or refer to chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	25 mg
calcium amino acid chelate	25 mg
Equivalent: calcium	5 mg
calcium pantothenate	43.67 mg
Equivalent: pantothenic acid	40 mg
cyanocobalamin	200 microgram
d-alpha-tocopheryl acid succinate	21 mg
Equivalent: d-alpha-tocopherol	25 IU
folic acid	200 microgram
magnesium amino acid chelate	500 mg
Equivalent: magnesium	80 mg
magnesium aspartate dihydrate	94.9 mg
Equivalent: magnesium	6.4 mg
magnesium orotate dihydrate	80 mg
Equivalent: magnesium	5.2 mg
nicotinamide	40 mg
potassium aspartate	120 mg
Equivalent: potassium	26 mg
pyridoxine hydrochloride	25 mg
Equivalent: pyridoxine	20.57 mg
riboflavin	10 mg
taurine	50 mg
thiamine hydrochloride	20 mg
Equivalent: thiamine	17.84 mg
zinc amino acid chelate	25 mg

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Equivalent: zinc

5 mg

Other Ingredients (Excipients)

Carnauba Wax

colloidal anhydrous silica

croscarmellose sodium

ethylcellulose

hypromellose

macrogol 400

magnesium stearate

microcrystalline cellulose

tapioca starch

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