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

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

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 chronic fatigue syndrome.

Product presentation must not imply or refer to serious immunological diseases.

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.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

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.

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**
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
ethylcellulose
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
tapioca starch