



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	314036	NUTRA-LIFE MAGNESIUM COMPLETE FORTE
ARTG entry for	Medicine Listed	
Sponsor	Vitaco Health Australia Pty Ltd	
Postal Address	PO Box 399, NORTH RYDE BC, NSW, 1670 Australia	
ARTG Start Date	8/02/2019	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . NUTRA-LIFE MAGNESIUM COMPLETE FORTE

Product Type	Single Medicine Product	Effective Date	8/02/2019
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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 healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support body electrolyte balance
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support healthy teeth
- Maintain/support nail health/strength/thickness
- Maintain/support bone health
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle function
- Maintain/support healthy neuromuscular system/function

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Aid/assist/helps protein synthesis in the body
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
 Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
 Maintain/support cognitive function/mental function in healthy adults
 Maintain/support nerve conduction
 Maintain/support nervous system health
 Maintain/support nervous system function
 Maintain/support female reproductive system health
 Maintain/support reproductive system health in males
 Maintain/support healthy reproductive hormones
 Maintain/support sperm health in healthy males
 Maintain/support sperm production in healthy males
 Maintain/support testosterone level
 Maintain/support skin health
 Maintain/support skin integrity/structure
 Maintain/support skin regeneration
 Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to infertility.
 Product presentation must not imply or refer to hormone imbalances.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 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 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.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to serious immunological diseases.
 Label statement: 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.

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
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

magnesium amino acid chelate	135 mg
Equivalent: magnesium	27 mg
magnesium oxide	574.5 mg
Equivalent: magnesium	337 mg

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magnesium phosphate pentahydrate	174.17 mg
Equivalent: magnesium	36 mg
zinc oxide	2.49 mg
Equivalent: zinc	2 mg

Other Ingredients (Excipients)

- Gelatin
- magnesium stearate
- microcrystalline cellulose
- purified water
- sodium lauryl sulfate

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