



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	297965	ETHICAL NUTRIENTS MEGA MAGNESIUM
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	22/12/2017	
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.

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 . ETHICAL NUTRIENTS MEGA MAGNESIUM

Product Type	Single Medicine Product	Effective Date	17/06/2020
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Permitted Indications

- Maintain/support energy levels
- Maintain/support general health and wellbeing
- Maintain/support cardiovascular system health
- Decrease/reduce/relieve muscle cramps
- Helps decrease/reduce/relieve mild muscle spasms/twitches
- Maintain/support healthy muscle contraction function
- Maintain/support muscle function
- Maintain/support healthy neuromuscular system/function
- Maintain/support muscle relaxation
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Support healthy stress response in the body
- Decrease/reduce/relieve menstruation pain/dysmenorrhoea
- Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

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

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

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

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

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).



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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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. If symptoms persist consult your healthcare practitioner (or words to that effect).
 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.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

chromic chloride hexahydrate	1 mg
Equivalent: chromium	200 microgram
magnesium amino acid chelate	500 mg
Equivalent: magnesium	50 mg
magnesium amino acid chelate	750 mg
Equivalent: magnesium	150 mg
pyridoxine hydrochloride	16.6 mg
Equivalent: pyridoxine	13.7 mg
selenomethionine	33 microgram
Equivalent: selenium	13 microgram
zinc sulfate monohydrate	19 mg
Equivalent: zinc	7 mg

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- chlorophyllin-copper complex
- croscarmellose sodium
- hypolose
- macrogol 8000
- magnesium stearate
- microcrystalline cellulose
- silicon dioxide
- stearic acid

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