



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	300616	Magnesium Excel
ARTG entry for	Medicine Listed	
Sponsor	Global Therapeutics Pty Ltd	
Postal Address	PO Box 1999, BYRON BAY, NSW, 2481 Australia	
ARTG Start Date	9/03/2018	
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.

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 . Magnesium Excel

Product Type	Single Medicine Product	Effective Date	14/12/2019
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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 physical endurance/capacity/stamina when dietary intake is inadequate
- Maintain/support heat/energy production/thermogenesis
- Maintain/support body electrolyte balance after exercise
- Helps restore body electrolyte balance
- Maintain/support bone health
- Maintain/support cardiovascular system health when dietary intake is inadequate
- Maintain/support healthy cardiovascular system function when dietary intake is inadequate
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Decrease/reduce/relieve muscle cramps when dietary intake is inadequate
- Helps reduce occurrence of muscle cramp when dietary intake is inadequate
- Helps decrease/reduce/relieve mild muscle spasms/twitches when dietary intake is inadequate
- Maintain/support healthy muscle contraction function
- Maintain/support muscle function
- Maintain/support healthy neuromuscular system/function
- Maintain/support muscle relaxation

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Maintain/support muscle relaxation when dietary intake is inadequate
 Maintain/support muscle strength when dietary intake is inadequate
 Decrease/reduce/relieve muscle tiredness when dietary intake is inadequate
 Maintain/support muscle performance/endurance/stamina
 Helps enhance/improve/promote/increase physical/exercise performance when dietary intake is inadequate
 Aid/assist/helps glucose/sugar/carbohydrate metabolism
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
 Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
 Support healthy stress response in the body
 Decrease/reduce/relieve restlessness/excess nervous energy when dietary intake is inadequate
 Maintain/support nerve conduction
 Maintain/support neuromuscular function
 Decrease/reduce/relieve sleeplessness when dietary intake is inadequate
 Maintain/support healthy sleeping patterns when dietary intake is inadequate
 Decrease/reduce feelings of aggression/irritability associated with premenstrual tension
 Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
 Decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension
 Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to serious cardiovascular conditions.
 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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
 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.
 If product is indicated for supplementation, 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.
 Product presentation must not imply or refer to serious immunological diseases.
 If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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.
 This product 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.
 (If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral

Visual Identification

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Active Ingredients

ascorbic acid	25 mg/g
Biotin	20 microgram/g
calcium pantothenate	5 mg/g
choline bitartrate	5 mg/g
chromium picolinate	40.2 microgram/g
Equivalent: chromium	5 microgram/g
Cocos nucifera	80 mg/g
Equivalent: Cocos nucifera	2 g/g
cyanocobalamin	30 microgram/g
folic acid	30 microgram/g
glutamine	80 mg/g
inositol	5 mg/g
levocarnitine hydrochloride	24.4 mg/g
Equivalent: levocarnitine	20 mg/g
magnesium glycinate	448 mg/g
Equivalent: magnesium	60 mg/g
nicotinamide	5 mg/g
pyridoxine hydrochloride	5 mg/g
Equivalent: pyridoxine	4.1 mg/g
riboflavin	1 mg/g
selenomethionine	12.5 microgram/g
Equivalent: selenium	5 microgram/g
taurine	100 mg/g
thiamine hydrochloride	5 mg/g
zinc glycinate	8.59 mg/g
Equivalent: zinc	2.5 mg/g

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
citric acid
colloidal anhydrous silica
Flavour
glucose monohydrate
malic acid
maltodextrin
thaumatin
Water melon

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