



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	306909	Magnesium Excel Lemon Lime
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 Australia	
ARTG Start Date	11/07/2018	
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 Lemon Lime

Product Type	Single Medicine Product	Effective Date	30/08/2018
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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 health
- Maintain/support muscle function
- Maintain/support healthy neuromuscular system/function

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Maintain/support muscle relaxation when dietary intake is inadequate
 Maintain/support muscle relaxation
 Maintain/support muscle strength when dietary intake is inadequate
 Decrease/reduce/relieve muscle tiredness when dietary intake is inadequate
 Maintain/support muscle performance/endorance/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
 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 cardiovascular conditions.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Label statement: If symptoms persist, talk to your health professional.
 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/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 serious immunological diseases.
 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 musculoskeletal or neurological conditions.
 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

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.
 (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

Active Ingredients

ascorbic acid	22.73 mg/g
Biotin	.02 mg/g



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calcium pantothenate	4.55 mg/g
Equivalent: pantothenic acid	4.16 mg/g
choline bitartrate	4.59 mg/g
Equivalent: choline	4.55 mg/g
chromium picolinate	.037 mg/g
Equivalent: chromium	.0045 mg/g
Cocos nucifera fruit Juice concentrate	72.73 mg/g
Equivalent: Cocos nucifera (Juice fresh)	1.818 g/g
cyanocobalamin	26.92 microgram/g
folic acid	26.92 microgram/g
glutamine	72.72 mg/g
inositol	4.55 mg/g
levocarnitine hydrochloride	22.18 mg/g
Equivalent: levocarnitine	18.18 mg/g
magnesium glycinate	407.06 mg/g
Equivalent: magnesium	54.55 mg/g
nicotinamide	4.55 mg/g
pyridoxine hydrochloride	4.55 mg/g
Equivalent: pyridoxine	3.74 mg/g
riboflavin	.91 mg/g
selenomethionine	.011 mg/g
Equivalent: selenium	.0044 mg/g
taurine	90.91 mg/g
thiamine hydrochloride	4.54 mg/g
Equivalent: thiamine	3.58 mg/g
zinc glycinate	7.81 mg/g
Equivalent: zinc	2.26 mg/g
Other Ingredients (Excipients)	
citric acid	
colloidal anhydrous silica	
Flavour	
glucose monohydrate	
glycine	
maltodextrin	
silicon dioxide	
thaumatin	

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