



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	300618	Magnesium Excel
ARTG entry for	Medicine Listed	
Sponsor	McPherson's Consumer Products Pty Ltd	
Postal Address	Locked Bag 5018, Kingsgrove, NSW, 2208 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.

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	7/05/2020
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Permitted Indications

- 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
- 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
- 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
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Decrease/reduce/relieve restlessness/excess nervous energy when dietary intake is inadequate
- Maintain/support nerve conduction
- Maintain/support neuromuscular function

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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

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 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.
 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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
 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.
 Product presentation must not imply or refer to serious cardiovascular conditions.
 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.

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	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

magnesium amino acid chelate	300 mg
Equivalent: magnesium	60 mg
magnesium aspartate tetrahydrate	150 mg
Equivalent: magnesium	10 mg
magnesium citrate	389 mg
Equivalent: magnesium	60 mg
magnesium glycinate	491.28 mg
Equivalent: magnesium	70 mg

Other Ingredients (Excipients)

Carnauba Wax
citric acid
colloidal anhydrous silica
croscarmellose sodium

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hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
titanium dioxide

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