

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	300618	Magnesium Excel		
ARTG entry for	Medicine Listed			
Sponsor	McPherson's Co	nsumer Products Pty Ltd		
Postal Address	Locked Bag 5018 Australia	3, Kingsgrove, NSW, 2208		
ARTG Start Date	9/03/2018			
Product Category	Medicine			
Status	Active			
Approval Area	Listed Medicines			
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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.

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	16/01/2023			
Permitted Indicatio	ns					
Maintain/support phy	vsical endurance/capacity/stamina when dietary inta	ake is inadequate				
Decrease/reduce/rel	ieve symptoms of premenstrual tension					
Maintain/support boo	ly electrolyte balance after exercise					
Helps restore body e	lectrolyte balance					
Maintain/support bor	ne health					
Maintain/support car	diovascular system health when dietary intake is in	adequate				
Maintain/support hea	althy cardiovascular system function when dietary in	ntake is inadequate				
Decrease/reduce/rel	ieve muscle cramps when dietary intake is inadequ	ate				
Helps reduce occurr	ence of muscle cramp when dietary intake is inaded	quate				
Helps decrease/redu	ce/relieve mild muscle spasms/twitches when dieta	ary intake is inadequate				
Maintain/support hea	althy muscle contraction function					
Maintain/support mu	scle function					
Maintain/support hea	althy neuromuscular system/function					
Maintain/support mu	scle relaxation					
Maintain/support mu	scle 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 ner	ve conduction					
Maintain/support neu	Iromuscular 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/rel	Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension					

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Decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension

Maintain/support heat/energy production/thermogenesis

Indication Requirements

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

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 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.

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 chronic fatigue syndrome.

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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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	on		
Pack Size		Poison Schedule	
Components			
1. Formulation 1			
Dosage Form	Tablet, film coated		
Route of Administration	Oral		
Visual Identification			
Active Ingredients			
magnesium amino acid c	helate	300 mg	
Equivalent: magnesium		60 mg	
magnesium aspartate tetr	rahydrate	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 (Excipi	ents)		
Carnauba Wax			
citric acid			
colloidal anhydrous silica	i		
croscarmellose sodium			
hypromellose			
macrogol 400			
magnesium stearate			

Page 2 of 3

microcrystalline cellulose

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