

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	373063	Mg Trilogy		
ARTG entry for	Medicine Listed	0 07		
	Medicine Listed			
Sponsor	Greal Labs Pty Ltd			
Postal Address	PO Box 193, Fitzroy, VIC, 3065			
	Australia			
ARTG Start Date	18/08/2021			
Product Category	Medicine			
Status	Active			
Approval Area	Listed Medicines	s		

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. Mg Trilogy Product Type Single Medicine Product Effective Date 5/12/2022 Permitted Indications Maintain/support general health and wellbeing Maintain/support bone health Maintain/support bone health Maintain/support bone health Maintain/support bone mass/density/integrity Maintain/support cardiovascular system health when dietary intake is inadequate Decrease/reduce/relieve muscle cramps when dietary intake is inadequate Helps decrease/reduce/relieve mild muscle spasms/twitches when dietary intake is inadequate Maintain/support muscle health Maintain/support muscle function Enhance/improve/promote/increase muscle relaxation
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Maintain/support muscle function
Enhance/improve/promote/increases muscle relevation
Enhance/improve/promote/increase muscle relaxation
Aid/assist/helps post exercise recovery
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Decrease/reduce/relieve nervous tension/unrest
Maintain/support nervous system health when dietary intake is inadequate

Decrease/reduce/relieve sleeplessness

Enhance/improve/promote/increase sleep quality/deep sleep

Indication Requirements

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 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.

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

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).

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

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

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

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.

Additional Product information

Pack Size/Poison information		
Pack Size		Poison Schedule
Components		
1. Formulation 1		
Dosage Form	Capsule, hard	
Route of Administration	Oral	
Visual Identification		
Active Ingredients		
magnesium citrate		138.23 mg
Equivalent: magnesium		20.73 mg
magnesium glycerophosphate		138.23 mg
Equivalent: magnesium		15.2 mg
magnesium glycinate		576.43 mg
Equivalent: magnesium		69.17 mg
Other Ingredients (Excipie	ents)	
carrageenan		
colloidal anhydrous silica	l	
hypromellose		
magnesium stearate		
microcrystalline cellulose		
potassium acetate		
purified water		

Public Summar

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