



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	294471	Tri-Magnesium Citrate 900 mg
ARTG entry for	Medicine Listed	
Sponsor	Phytologic Holdings Pty Ltd	
Postal Address	16-20 Baker Street, Banksmeadow, NSW, 2019 Australia	
ARTG Start Date	29/09/2017	
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.

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 . Tri-Magnesium Citrate 900 mg

Product Type	Single Medicine Product	Effective Date	6/11/2020
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Permitted Indications

Maintain/support energy levels when dietary intake is inadequate
Maintain/support energy production
Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate
Maintain/support general health and wellbeing
Maintain/support cardiovascular system health
Maintain/support heart health
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 muscle health
Maintain/support muscle function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when dietary intake is inadequate
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support nervous system health
Maintain/support nervous system function

Indication Requirements

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.

Product presentation must not imply or refer to chronic fatigue syndrome.

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

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

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.



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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 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).

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).

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	900 mg
Equivalent: magnesium	139.05 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

hypromellose

magnesium stearate

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