

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	216265	BLOOMS MAGNESIUM COMPLEX POWDER	
ARTG entry for	Medicine Listed		
Sponsor	Phytologic Holdings Pty Ltd		
Postal Address	PO Box 6193, Alexandria, NSW, 2015 Australia		
ARTG Start Date	21/10/2013		
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

Product Type	Single Medicine Product	Effective Date	11/02/2021
Permitted Indication	ons		
Maintain/support er	nergy levels		
Maintain/support er	nergy production		
Maintain/support ge	eneral health and wellbeing		
Maintain/support bo	one health		
Aids/assists healthy	/ bone development/growth/building		
Help maintain/supp	ort bone mineralisation		
Maintain/support ca	ardiovascular system health		
Maintain/support he	ealthy cardiovascular system function		
Maintain/support he	eart health		
Helps enhance/imp	rove/promote immune system function		
Maintain/support he	ealthy immune system function		
Decrease/reduce/re	elieve muscle cramps		
Helps decrease/rec	luce/relieve mild muscle spasms/twitches		
Maintain/support he	ealthy muscle contraction function		
Maintain/support m	uscle function		
Aid/assist/helps in t	he healing of minor muscle injuries		
Helps decrease/rec	luce/relieve symptoms of muscle sprain/strain		
Decrease/reduce/re	elieve muscle pain/ache/soreness		
Decrease/reduce/re	elieve muscle tension/stiffness		
Aid/assist/helps pos	st exercise recovery		
Maintain/support (s	tate vitamin/mineral/nutrient) levels in the body		
Helps prevent dieta	ry (state vitamin/mineral/nutrient) deficiency		
Aid/assist/helps me	tabolism of (state vitamin/mineral/nutrient)		
Decrease/reduce/re	elieve symptoms of stress		
Decrease/reduce/re	elieve nervous tension/unrest		
Helps decrease/rec	luce/relieve symptoms of mild tension headache		
Maintain/support ne	ervous system health		
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Maintain/support nervous system function

Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

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

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 mental illnesses, disorders or conditions.

Product presentation must not imply or refer to serious immunological diseases.

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.

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.

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 musculoskeletal or neurological 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 can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size		Poison Schedule
Components		
1 . Formulation 1		
Dosage Form	Powder, oral	
Route of Administration	Oral	
Visual Identification		
Active Ingredients		
calcium ascorbate dihydrate		48.7 mg/g
Equivalent: calcium		4.58 mg/g
Equivalent: ascorbic acid		40 mg/g
glutamine		100 mg/g
magnesium amino acid chelate		343 mg/g
Equivalent: magnesium		68.6 mg/g
magnesium glycinate dihydrate		85.47 mg/g
Equivalent: magnesium		10 mg/g
magnesium orotate dihydrate		21.2 mg/g
Equivalent: magnesium		1.4 mg/g
potassium aspartate		77.3 mg/g
Equivalent: potassium		16 mg/g
taurine		200 mg/g
Other Ingredients (Excipie	ents)	
Acacia		

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