



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	164335	BLACKMORES BIO MAGNESIUM
ARTG entry for	Medicine Listed	
Sponsor	Blackmores Ltd	
Postal Address	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia	
ARTG Start Date	14/08/2009	
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 . BLACKMORES BIO MAGNESIUM

Product Type	Single Medicine Product	Effective Date	7/09/2022
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Permitted Indications

Maintain/support general health and wellbeing
Maintain/support bone health
Maintain/support heart health
Decrease/reduce/relieve muscle cramps when dietary intake is inadequate
Maintain/support muscle health
Maintain/support muscle function
Decrease/reduce/relieve muscle tension/stiffness when dietary intake is inadequate
Maintain/support nervous system health

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
[Contains vitamin B6].

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.



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Additional Product information		
Pack Size/Poison information		
Pack Size	Poison Schedule	
Components		
1 . Formulation 1		
Dosage Form	Tablet, film coated	
Route of Administration	Oral	
Visual Identification		
Active Ingredients		
calcium ascorbate dihydrate		50 mg
Equivalent: ascorbic acid		41.31 mg
colecalfiferol		.0025 mg
heavy magnesium oxide		440 mg
Equivalent: magnesium		265.3 mg
magnesium phosphate pentahydrate		175 mg
Equivalent: magnesium		36.2 mg
manganese amino acid chelate		40 mg
Equivalent: manganese		4 mg
pyridoxine hydrochloride		50 mg
Equivalent: pyridoxine		41.1 mg
Other Ingredients (Excipients)		
Carnauba Wax		
croscarmellose sodium		
dl-alpha-tocopherol		
hydrogenated soya oil		
hydrolysed gelatin		
hypromellose		
indigo carmine		
lecithin		
macrogol 3000		
macrogol 8000		
magnesium stearate		
maize starch		
microcrystalline cellulose		
polyvinyl alcohol		
purified talc		
silicon dioxide		
sucrose		
tartaric acid		
titanium dioxide		

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