

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

| Summary for ARTG Entry: | 288864 | BLACKMORES SUPER MAGNESIUM + |
|-------------------------|-----------------------------|------------------------------|
| ARTG entry for | Medicine Listed | |
| Sponsor | Blackmores Ltd | |
| Postal Address | PO Box 1725, W Australia | ARRIEWOOD, NSW, 2102 |
| ARTG Start Date | 12/05/2017 | |
| 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. BLACKMO | RES SUPER MAGNESIUM + | | | |
|----------------------|-------------------------------------------------|---------------------------------------|--------------------------------------|--|
| Product Type | Single Medicine Product | Effective Date | 8/09/2022 | |
| Permitted Indicat | ions | | | |
| Maintain/support e | nergy levels | | | |
| Relieve weariness, | /tiredness/fatigue/feeling of weakness when a | dietary intake is inadequate | | |
| Maintain/support b | ody electrolyte balance | | | |
| Maintain/support g | eneral health and wellbeing | | | |
| Maintain/support c | ardiovascular system health when dietary int | ake is inadequate | | |
| Decrease/reduce/r | elieve muscle cramps when dietary intake is | inadequate | | |
| Helps decrease/re | duce/relieve mild muscle spasms/twitches wh | nen dietary intake is inadequate | | |
| Maintain/support m | nuscle health | | | |
| Decrease/reduce/r | elieve muscle tension/stiffness when dietary | intake is inadequate | | |
| Maintain/support m | nuscle performance/endurance/stamina wher | n dietary intake is inadequate | | |
| Aid/assist/helps glu | ucose/sugar/carbohydrate metabolism | | | |
| Maintain/support n | ervous system health | | | |
| Maintain/support n | ervous system function | | | |
| Indication Requir | ements | | | |
| Product presentat | ion must not imply or refer to mental illnesses | s, disorders or conditions. | | |
| Product presentat | ion must not imply or refer to lowering or rais | ing blood sugar/glucose levels from a | outside of the normal healthy range. | |
| Label statement: I | f symptoms persist, talk to your health profes | sional. | | |
| Product presentat | ion must not imply or refer to serious muscul | oskeletal or neurological conditions. | | |
| Product presentat | ion must not imply or refer to serious cardiov | ascular conditions. | | |
| | | | | |

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

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

Additional Product information

| ack Size | | Poison Schedule | |
|----------------------------|---------------------|------------------|--|
| omponents | | | |
| 1. Formulation 1 | | | |
| Dosage Form | Tablet, film coated | | |
| Route of Administration | Oral | | |
| Visual Identification | Orai | | |
| Active Ingredients | | | |
| - | | 20 50 | |
| calcium ascorbate dihydra | te | 60.52 mg | |
| Equivalent: ascorbic acid | | 50 mg | |
| Equivalent: calcium | | 5.69 mg | |
| chromium picolinate | | 402.25 microgram | |
| Equivalent: chromium | | 50 microgram | |
| colecalciferol | | .0025 mg | |
| heavy magnesium oxide | | 423.22 mg | |
| Equivalent: magnesium | | 245 mg | |
| magnesium amino acid ch | elate | 75 mg | |
| Equivalent: magnesium | | 15 mg | |
| magnesium citrate | | 291.26 mg | |
| Equivalent: magnesium | | 45 mg | |
| manganese amino acid che | elate | 40 mg | |
| Equivalent: manganese | | 4 mg | |
| pyridoxine hydrochloride | | 60.78 mg | |
| Equivalent: pyridoxine | | 50 mg | |
| Other Ingredients (Excipie | nts) | | |
| Acacia | | | |
| calcium hydrogen phospha | ate dihydrate | | |
| Carnauba Wax | | | |
| colloidal anhydrous silica | | | |
| croscarmellose sodium | | | |
| dl-alpha-tocopherol | | | |
| hypromellose | | | |
| macrogol 8000 | | | |
| magnesium stearate | | | |
| maize starch | | | |
| medium chain triglycerides | 3 | | |
| microcrystalline cellulose | | | |
| silicon dioxide | | | |
| soy polysaccharide | | | |
| | | | |
| sucrose tartaric acid | | | |

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