



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|-------------------------------|
| Summary for ARTG Entry: | 394770 | PURE Mg+ Magnesium Switch Off |
| ARTG entry for | Medicine Listed | |
| Sponsor | SFI Australasia | |
| Postal Address | Level 2 / 170 Pacific Highway, St. Leonards, NSW, 2065 Australia | |
| ARTG Start Date | 26/08/2022 | |
| 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 . PURE Mg+ Magnesium Switch Off

| Product Type | Single Medicine Product | Effective Date | 25/01/2024 |
|--------------|-------------------------|----------------|------------|
|--------------|-------------------------|----------------|------------|

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
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support body electrolyte balance
- Maintain/support bone health
- Maintain/support bone mass/density/integrity
- Help maintain/support bone mineralisation
- Helps maintain/support healthy blood sugar/glucose
- Maintain/support cardiovascular system health
- Helps maintain/support healthy heart function
- Maintain/support healthy cardiovascular system function
- 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 healthy muscle contraction function
- Maintain/support muscle function
- Maintain/support healthy neuromuscular system/function
- Maintain/support muscle relaxation
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Calms the mind
- Calms the mind in peri-menopausal women
- Help maintain/support emotional wellbeing
- Help maintain/support emotional wellbeing in peri-menopausal women

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- Soothe/calm nerves
- Soothe/calm nerves in peri-menopausal women
- Decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve nervous tension/unrest
- Decrease/reduce/relieve nervous tension/unrest in peri-menopausal women
- Decrease/reduce/relieve symptoms of mild anxiety
- Decrease/reduce/relieve symptoms of mild anxiety in peri-menopausal women
- Maintain/support general mental wellbeing
- Maintain/support general mental wellbeing in peri-menopausal women
- Maintain/support nervous system health
- Maintain/support nervous system function
- Support healthy emotional/mood balance
- Support healthy emotional/mood balance in peri-menopausal women
- Decrease/reduce/relieve sleeplessness when dietary intake is inadequate
- Enhance/improve/promote/increase sleep quality/deep sleep
- Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to serious cardiovascular conditions.
 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 musculoskeletal or neurological conditions.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 Product presentation must only refer to mild anxiety.
 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 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

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|------------------|------------------------|
| Pack Size | Poison Schedule |
|------------------|------------------------|

Components

1 . Formulation 1

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|--------------------------------|--------------|
| Dosage Form | Powder, oral |
| Route of Administration | Oral |

Visual Identification

Active Ingredients

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|--|--------------------|
| Crocus sativus stigma Extract dry concentrate | 2.55 mg/g |
| Equivalent: Crocus sativus (Dry) | 7.64 mg/g |
| glycine | 363.64 mg/g |
| magnesium amino acid chelate | 106.05 mg/g |
| Equivalent: magnesium | 21.21 mg/g |

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| magnesium citrate | 132.63 mg/g |
| Equivalent: magnesium | 21.22 mg/g |
| magnesium glycinate | 151.5 mg/g |
| Equivalent: magnesium | 21.21 mg/g |

Other Ingredients (Excipients)

- citric acid
- colloidal anhydrous silica
- Flavour
- glycine
- Stevia rebaudiana

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