



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|----------|
| Summary for ARTG Entry: | 375975 | MagRelax |
| ARTG entry for | Medicine Listed | |
| Sponsor | Give Back Health Pty Ltd | |
| Postal Address | 10/5 Canopus Street, Bridgeman Downs, QLD, 4035 Australia | |
| ARTG Start Date | 8/10/2021 | |
| 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 . MagRelax

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 8/10/2021 |
|---------------------|-------------------------|-----------------------|-----------|

Permitted Indications

Maintain/support general health and wellbeing
Maintain/support healthy teeth
Maintain/support bone health
Help maintain/support bone mineralisation
Maintain/support heart health
Maintain/support muscle health
Maintain/support muscle function
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Maintain/support (state vitamin/mineral) within normal range
Maintain/support neuromuscular function
Maintain/support nervous system health
Enhance/promote/increase refreshing sleep
Maintains/supports refreshing sleep
Decrease/reduce time to fall asleep
Decrease/reduce/relieve disturbed/restless sleep
Enhance/promote/increase healthy sleep patterns
Maintain/support healthy sleeping patterns

Indication Requirements

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.

Product presentation must not imply or refer to serious cardiovascular conditions.

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

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is



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inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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).

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

| | |
|--------------------------|--------------------|
| glycine | 566.04 mg/g |
| magnesium citrate | 426.05 mg/g |
| Equivalent: magnesium | 66.04 mg/g |

Other Ingredients (Excipients)

colloidal anhydrous silica
glycine

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