



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	430471	Sleep & Relax (Magnesium + Ashwagandha)
ARTG entry for	Medicine Listed	
Sponsor	Nature's Care Manufacture Pty Limited	
Postal Address	5 Minna Close, BELROSE, NSW, 2085 Australia	
ARTG Start Date	10/12/2023	
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 . Sleep & Relax (Magnesium + Ashwagandha)

Product Type	Single Medicine Product	Effective Date	10/12/2023
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Permitted Indications

- Maintain/support general health and wellbeing
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Help maintain/support emotional wellbeing
- Traditionally used in Western herbal medicine to help maintain/support emotional wellbeing
- Traditionally used in Western herbal medicine to aid/assist/helps mind relaxation
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
- Maintain/support nervous system health
- Traditionally used in Western herbal medicine to support healthy emotional/mood balance
- Support healthy emotional/mood balance
- Traditionally used in Western herbal medicine to soporific/induces sleep
- Enhance/promote/increase refreshing sleep
- Maintains/supports refreshing sleep
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
- Maintain/support healthy sleeping patterns
- Traditionally used in Western herbal medicine to enhance/improve/promote/increase sleep quality/deep sleep
- Enhance/improve/promote/increase sleep quality/deep sleep

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.

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 only refer to mild anxiety.

Standard Indications



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No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist, seek the advice of a healthcare professional.

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.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

magnesium amino acid chelate **500 mg**

Equivalent: magnesium 100 mg

Magnolia officinalis stem bark Extract dry concentrate **75 mg**

Equivalent: Magnolia officinalis (Dry) 1.5 g

Matricaria chamomilla flower Extract dry concentrate **50 mg**

Equivalent: Matricaria chamomilla (Dry) 500 mg

Passiflora incarnata herb Extract dry concentrate **50 mg**

Equivalent: Passiflora incarnata (Dry) 1 g

pyridoxine hydrochloride **2.5 mg**

Equivalent: pyridoxine 2.06 mg

Withania somnifera root Extract dry concentrate **66.67 mg**

Equivalent: Withania somnifera (Dry) 3 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

Gelatin

magnesium stearate

maltodextrin

purified water

sodium lauryl sulfate

titanium dioxide

Public Summary

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