



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	386866	Henry Blooms Magnesium + Sleep Tablet
ARTG entry for	Medicine Listed	
Sponsor	Phytologic Holdings Pty Limited	
Postal Address	16-20 Baker Street, Banksmeadow, NSW, 2019 Australia	
ARTG Start Date	8/04/2022	
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 . Henry Blooms Magnesium + Sleep Tablet

Product Type	Single Medicine Product	Effective Date	8/04/2022
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Permitted Indications

Decrease/reduce/relieve muscle cramps when dietary intake is inadequate
Helps decrease/reduce/relieve mild muscle spasms/twitches when dietary intake is inadequate
Maintain/support muscle health
Maintain/support muscle function
Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
Decrease/reduce/relieve symptoms of stress
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
Maintain/support nervous system health
Maintain/support nervous system function
Traditionally used in Western herbal medicine to soporific/induces sleep
Traditionally used in Western herbal medicine to decrease/reduce time to fall asleep
Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep
Traditionally used in Western herbal medicine to enhance/improve/promote/increase sleep quality/deep sleep

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

Adults only.
 Not recommended for use by pregnant and lactating women (or words to that effect).

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

colecalfiferol	.005 mg
Eschscholzia californica herb flowering Extract dry concentrate	33.34 mg
Equivalent: Eschscholzia californica (Dry)	500.1 mg
magnesium amino acid chelate	550 mg
Equivalent: magnesium	110 mg
magnesium citrate	323.62 mg
Equivalent: magnesium	50 mg
Magnolia officinalis stem bark Extract dry concentrate standardised	35.75 mg
Equivalent: Magnolia officinalis (Dry)	357.5 mg
Equivalent: honokiol (of Magnolia officinalis) ()	1.95 mg
Phellodendron amurense stem bark Extract dry concentrate standardised	11.7 mg
Equivalent: Phellodendron amurense (Dry)	128.7 mg
Equivalent: berberine ()	.13 mg

Other Ingredients (Excipients)

- Acacia
- Carnauba Wax
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- d-alpha-tocopherol
- fractionated coconut oil
- high amylose maize starch
- hypromellose
- liquid glucose
- macrogol 400
- magnesium stearate
- maize starch
- microcrystalline cellulose
- povidone
- pregelatinised rice starch
- silicon dioxide
- sodium ascorbate
- titanium dioxide

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