



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	387049	Henry Blooms Magnesium + Sleep Powder
ARTG entry for	Medicine Listed	
Sponsor	Phytologic Holdings Pty Limited	
Postal Address	16-20 Baker Street, Banksmeadow, NSW, 2019 Australia	
ARTG Start Date	13/04/2022	
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 Powder

Product Type	Single Medicine Product	Effective Date	13/04/2022
---------------------	-------------------------	-----------------------	------------

Permitted Indications

- Maintain/support general health and wellbeing
- 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)
- Decrease/reduce/relieve symptoms of stress
- Traditionally used in Western herbal medicine to 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

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

Standard Indications

No Standard Indications included on Record

Specific Indications



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

No Specific Indications included on Record

Warnings

Not recommended for use during pregnancy or lactation
Adults only.

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

colecalfiferol	.002 mg/g
Eschscholzia californica herb flowering Extract dry concentrate	13.34 mg/g
Equivalent: Eschscholzia californica (Dry)	200.1 mg/g
magnesium amino acid chelate	300 mg/g
Equivalent: magnesium	60 mg/g
magnesium citrate	181.23 mg/g
Equivalent: magnesium	28 mg/g
Magnolia officinalis stem bark Extract dry concentrate standardised	14.3 mg/g
Equivalent: honokiol (of Magnolia officinalis) ()	.78 mg/g
Equivalent: Magnolia officinalis (Dry)	143 mg/g
Phellodendron amurense stem bark Extract dry concentrate standardised	4.68 mg/g
Equivalent: berberine ()	.052 mg/g
Equivalent: Phellodendron amurense (Dry)	51.48 mg/g

Other Ingredients (Excipients)

Acacia

citric acid

colloidal anhydrous silica

d-alpha-tocopherol

Flavour

fractionated coconut oil

glycine

high amylose maize starch

liquid glucose

maize starch

silicon dioxide

sodium ascorbate

Stevia rebaudiana

Public Summary

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.