



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	357370	He Deep Sleep Formula
ARTG entry for	Medicine Listed	
Sponsor	Martin & Pleasance Pty Ltd	
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
ARTG Start Date	23/03/2021	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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 . He Deep Sleep Formula

Product Type	Single Medicine Product	Effective Date	23/03/2021
---------------------	-------------------------	-----------------------	------------

Permitted Indications

- Enhance/promote energy levels
- Maintain/support energy levels
- Maintain/support body electrolyte balance
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support muscle function
- Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body
- 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
- Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
- Traditionally used in Chinese medicine to decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Western herbal medicine to calmative/nervous system relaxant
- Traditionally used in Western herbal medicine to soporific/induces sleep
- Traditionally used in Chinese medicine to soporific/induces sleep
- Traditionally used in Chinese medicine to enhance/promote/increase refreshing sleep
- Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Chinese medicine to decrease/reduce/relieve disturbed/restless sleep
- Traditionally used in Chinese medicine to enhance/improve/promote/increase sleep quality/deep sleep

Indication Requirements

Product presentation must not imply or refer to chronic fatigue syndrome.

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

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 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.



Australian Government
Department of Health
Therapeutic Goods Administration

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

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

magnesium citrate	185.61 mg
Equivalent: magnesium	30 mg
magnesium glycinate	187.5 mg
Equivalent: magnesium	22.5 mg
Passiflora incarnata herb top Extract dry concentrate	50 mg
Equivalent: Passiflora incarnata (Dry)	1 g
Prunus cerasus fruit Extract dry concentrate	60 mg
Equivalent: Prunus cerasus (Dry)	600 mg
pyridoxal 5-phosphate	1.24 mg
Equivalent: pyridoxine	850 microgram
Ziziphus jujuba var. spinosa seed Extract dry concentrate	250 mg
Equivalent: Ziziphus jujuba var. spinosa (Dry)	5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
hypromellose
magnesium stearate
microcrystalline cellulose

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>.