



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	427790	Stress and Sleep Support
ARTG entry for	Medicine Listed	
Sponsor	Honest Health Co Pty Ltd	
Postal Address	44 Seabrook Street, Elanora, QLD, 4221 Australia	
ARTG Start Date	13/11/2023	
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 . Stress and Sleep Support

Product Type	Single Medicine Product	Effective Date	13/11/2023
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Permitted Indications

- Maintain/support healthy muscle contraction function
- Maintain/support muscle function
- Maintain/support muscle relaxation
- Support healthy stress response in the body
- Traditionally used in Western herbal medicine to calms the mind
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
 - Linked indication - Decrease/reduce/relieve disturbed/restless sleep
- Maintain/support nervous system function
- Maintain/support healthy sleeping patterns
- 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.

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
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Components

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1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

glycine	272.73 mg/g
magnesium glycinate dihydrate	279.12 mg/g
Equivalent: magnesium	31.82 mg/g
Passiflora incarnata herb top Extract dry concentrate	36.36 mg/g
Equivalent: Passiflora incarnata (Dry)	363.6 mg/g
Withania somnifera root Extract dry concentrate	54.55 mg/g
Equivalent: Withania somnifera (Dry)	545.5 mg/g

Other Ingredients (Excipients)

Beta vulgaris
citric acid
colloidal anhydrous silica
Flavour
glycine
maltodextrin
Stevia rebaudiana

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