



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	319651	Neuro Sleep
ARTG entry for	Medicine Listed	
Sponsor	Biomedica Nutraceuticals Pty Ltd	
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	3/07/2019	
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 . Neuro Sleep

Product Type	Single Medicine Product	Effective Date	26/03/2025
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Permitted Indications

Maintain/support general health and wellbeing
Support healthy stress response in the body
Traditionally used in Western herbal medicine to decrease/reduce/relieve restlessness/excess nervous energy
Traditionally used in Western herbal medicine to soothe/calm nerves
Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
Aid/assist/helps synthesis of neurotransmitters
Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
Maintain/support healthy sleeping patterns

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

In rare cases, valerian may harm the liver. Stop use and see a doctor if you have yellowing skin/eyes or unusual: fatigue, nausea, appetite loss, abdominal pain, dark urine or itching.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1



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Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Humulus lupulus fruit Extract dry concentrate	62.5 mg
Equivalent: Humulus lupulus (Dry)	625 mg
magnesium amino acid chelate	262.5 mg
Equivalent: magnesium	52.5 mg
Passiflora incarnata herb top flowering Extract dry concentrate	100 mg
Equivalent: Passiflora incarnata (Dry)	2 g
Valeriana officinalis root Extract dry concentrate	200 mg
Equivalent: Valeriana officinalis (Dry)	1 g

Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
Lavender Oil
maltodextrin
microcrystalline cellulose
stearic acid

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