



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	319651	Neuro Sleep
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Biomedica Nutraceuticals Pty Ltd	
<b>Postal Address</b>	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
<b>ARTG Start Date</b>	3/07/2019	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Neuro Sleep

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	3/07/2019
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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

No Warnings included on Record

### Additional Product information

### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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### Components

#### 1 . Formulation 1

<b>Dosage Form</b>	Capsule, hard
<b>Route of Administration</b>	Oral

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**Visual Identification**

**Active Ingredients**

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

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
hypromellose  
Lavender Oil  
maltodextrin  
microcrystalline cellulose  
stearic acid

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