



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

## Public Summary

<b>Summary for ARTG Entry:</b>	349930	Sleep Tablets
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Brauer Natural Medicine Pty Ltd	
<b>Postal Address</b>	PO Box 234, TANUNDA, SA, 5352 Australia	
<b>ARTG Start Date</b>	27/11/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Sleep Tablets

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/11/2020
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#### Permitted Indications

- Traditionally used in Homoeopathic medicine to relieve irritability
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve restlessness/excess nervous energy
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of stress
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mental overactivity
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve disturbed/restless sleep

#### Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must only refer to mild anxiety.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Homoeopathic product/preparation or medicine (or words to that effect)  
(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

#### Additional Product information

#### Pack Size/Poison information

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

##### 1 . Formulation 1



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**Dosage Form**                      Tablet, uncoated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Capsicum annuum fruit (Homeopathic)</b>	<b>392.72 microgram</b>
<b>Coffea arabica seed (Homeopathic)</b>	<b>392.72 microgram</b>
<b>Coffea arabica seed (Homeopathic)</b>	<b>392.72 microgram</b>
<b>Gelsemium sempervirens root and rhizome (Homeopathic)</b>	<b>392.72 microgram</b>
<b>Humulus lupulus fruit (Homeopathic)</b>	<b>392.72 microgram</b>
<b>Hyoscyamus niger whole plant (Homeopathic)</b>	<b>392.72 microgram</b>
Equivalent: Alkaloids calculated as hyoscyamine	0 microgram
Equivalent: Hyoscine	0 microgram
<b>Matricaria chamomilla whole plant (Homeopathic)</b>	<b>392.72 microgram</b>
<b>Passiflora incarnata herb flowering (Homeopathic)</b>	<b>392.72 microgram</b>
<b>Valeriana officinalis root and rhizome and stolon (Homeopathic)</b>	<b>392.72 microgram</b>

**Other Ingredients (Excipients)**

**glucose**

**magnesium stearate**

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