



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	386519	Nature's Sunshine Kava Calm & Sleep
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Nature's Sunshine Products of Australia Pty Ltd	
<b>Postal Address</b>	PO Box 6884, BAULKHAM HILLS BUSINESS CENTRE, NSW, 2153 Australia	
<b>ARTG Start Date</b>	31/03/2022	
<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 . Nature's Sunshine Kava Calm & Sleep

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	28/04/2023
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### Permitted Indications

- Traditionally used in Western herbal medicine to calms the mind
- 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 Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of mild anxiety
  - Linked indication - Help maintain/support emotional wellbeing
  - Linked indication - Calms the mind
  - Linked indication - Relieve irritability
  - Linked indication - Soothe/calm nerves
  - Linked indication - Decrease/reduce/relieve sleeplessness
  - Linked indication - Decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Western herbal medicine to soporific/induces sleep
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve disturbed/restless sleep
- Traditionally used in Western herbal medicine to enhance/promote/increase healthy sleep patterns
- Traditionally used in Western herbal medicine to enhance/improve/promote/increase sleep quality/deep 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

Not for prolonged use. If symptoms persist, seek advice from a health care practitioner. Not recommended for use by pregnant or lactating women (or words to that effect). May harm the liver.



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If symptoms persist consult your healthcare practitioner (or words to that effect).

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

**1 . Formulation 1**

**Dosage Form** Tablet, film coated

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Passiflora incarnata flower Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Passiflora incarnata (Dry)	1 g
<b>Piper methysticum rhizome Extract dry concentrate standardised</b>	<b>471 mg</b>
Equivalent: Piper methysticum (Dry)	1.884 g

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
calcium hydrogen phosphate  
Carnauba Wax  
chlorophyllin-copper complex  
colloidal anhydrous silica  
croscarmellose sodium  
crospovidone  
hypromellose  
macrogol 8000  
magnesium stearate  
maltodextrin  
microcrystalline cellulose  
povidone  
titanium dioxide

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