



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

## Public Summary

<b>Summary for ARTG Entry:</b>	346626	Kava Sleep
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Phytologic Holdings Pty Ltd	
<b>Postal Address</b>	16-20 Baker Street, Banksmeadow, NSW, 2019 Australia	
<b>ARTG Start Date</b>	27/10/2020	
<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 . Kava Sleep

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/10/2020
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#### Permitted Indications

- Maintain/support muscle relaxation
- Traditionally used in Pacific Islander medicine to aid/assist/helps mind relaxation
- Traditionally used in Western herbal medicine to soothe/calm nerves
- Traditionally used in Pacific Islander medicine to soothe/calm nerves
- Traditionally used in Pacific Islander medicine to enhance/improve/promote/increase body relaxation
- Traditionally used in Western herbal medicine to soporific/induces sleep
- Traditionally used in Pacific Islander medicine to soporific/induces sleep
- Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Pacific Islander medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Western herbal medicine to maintain/support urinary tract health

#### 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

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.

#### Additional Product information

#### Pack Size/Poison information

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

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>Piper methysticum root Extract dry concentrate standardised</b>	<b>600 mg</b>
Equivalent: Piper methysticum (Dry)	4.2 g

**Other Ingredients (Excipients)**

Acacia

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

magnesium stearate

microcrystalline cellulose

potable water

potassium acetate

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Public Summary