



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

## Public Summary

<b>Summary for ARTG Entry:</b>	367710	Mediherb Kava
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	1/06/2021	
<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 . Mediherb Kava

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	1/06/2021
---------------------	-------------------------	-----------------------	-----------

### Permitted Indications

Maintain/support general health and wellbeing  
Antispasmodic/spasmolytic  
Maintain/support muscle relaxation  
Help maintain/support emotional wellbeing  
Aid/assist/helps mind relaxation  
Traditionally used in Pacific Islander medicine to aid/assist/helps mind relaxation  
Decrease/reduce/relieve restlessness/excess nervous energy  
Decrease/reduce/relieve symptoms of stress  
Decrease/reduce/relieve nervous tension/unrest  
Decrease/reduce/relieve symptoms of mild anxiety  
Traditionally used in Pacific Islander medicine to calmative/nervous system relaxant  
Traditionally used in Pacific Islander medicine to soporific/induces sleep  
Maintains/supports refreshing sleep  
Decrease/reduce/relieve sleeplessness  
Decrease/reduce/relieve disturbed/restless sleep

### 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.  
Product presentation must only refer to mild anxiety.  
Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings



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

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

Not recommended for use by pregnant and lactating women (or words to that effect).

Do not use if pregnant or likely to become pregnant (or words to that effect)

Do not use while breastfeeding.

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.

If symptoms persist, seek the advice of a healthcare professional.

**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
-----------	-----------------

**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>Piper methysticum root and rhizome Extract dry concentrate standardised</b>	<b>455 mg</b>
Equivalent: Piper methysticum (Dry)	3.2 g

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
colloidal anhydrous silica  
hypromellose  
magnesium stearate  
microcrystalline cellulose  
sodium starch glycollate

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary