



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	389532 Thompson's One-A-Day Kava 3800
ARTG entry for	Medicine Listed
Sponsor	Integria Healthcare Australia Pty Ltd
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia
ARTG Start Date	3/06/2022
Product Category	Medicine
Status	Active
Approval Area	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 . Thompson's One-A-Day Kava 3800

Product Type	Single Medicine Product	Effective Date	3/06/2022
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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

Indication Requirements

Product presentation must only refer to mild anxiety.
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 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

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

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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

Piper methysticum root and rhizome Extract dry concentrate standardised 546 mg

Equivalent: Piper methysticum (Dry) 3.82 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

iron oxide black

lecithin

macrogol 3350

magnesium stearate

microcrystalline cellulose

polyvinyl alcohol

purified talc

sodium starch glycollate

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