



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|----------|
| Summary for ARTG Entry: | 400571 | KavaPlex |
| ARTG entry for | Medicine Listed | |
| Sponsor | Biomedica Nutraceuticals Pty Ltd | |
| Postal Address | PO Box 7052, ALEXANDRIA, NSW, 2015 Australia | |
| ARTG Start Date | 5/12/2022 | |
| 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 . KavaPlex

| | | | |
|---------------------|-------------------------|-----------------------|-----------|
| Product Type | Single Medicine Product | Effective Date | 5/12/2022 |
|---------------------|-------------------------|-----------------------|-----------|

Permitted Indications

Traditionally used in Native American medicine to analgesic/Anodyne/relieve pain

Maintain/support muscle relaxation

Decrease/reduce/relieve restlessness/excess nervous energy

Soothe/calm nerves

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.

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



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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|--|------------------|
| Eschscholzia californica herb flowering Extract dry concentrate | 208.33 mg |
| Equivalent: Eschscholzia californica (Dry) | 1.25 g |
| Passiflora incarnata herb Extract dry concentrate | 20 mg |
| Equivalent: Passiflora incarnata (Dry) | 2 g |
| Piper methysticum root and rhizome Extract dry concentrate standardised | 200 mg |
| Equivalent: Piper methysticum (Dry) | 3 g |

Other Ingredients (Excipients)

Acacia

calcium hydrogen phosphate dihydrate

carrageenan

colloidal anhydrous silica

hypromellose

Oryza sativa

potassium acetate

purified water

Sunflower Oil

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