



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	368196	CalmPlex
ARTG entry for	Medicine Listed	
Sponsor	Biomedica Nutraceuticals Pty Ltd	
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	4/06/2021	
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 . CalmPlex

Product Type	Single Medicine Product	Effective Date	4/04/2022
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Permitted Indications

Maintain/support general health and wellbeing
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
Maintain/support brain function
Aid/assist/helps synthesis of neurotransmitters
Traditionally used in Western herbal medicine to calmative/nervous system relaxant
Traditionally used in Western herbal medicine to nerve/support nervous system
Maintain/support nervous system function
Support healthy emotional/mood balance
Traditionally used in Western herbal medicine to support healthy emotional/mood balance
Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
[Contains vitamin B6].



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Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Lavandula angustifolia flower Oil essential	27 mg
Melissa officinalis herb Extract dry concentrate	130 mg
Equivalent: Melissa officinalis (Dry)	1.3 g
pyridoxal 5-phosphate monohydrate	7.84 mg
Equivalent: pyridoxine	5 mg
pyridoxine hydrochloride	6.08 mg
Equivalent: pyridoxine	5 mg
Scutellaria lateriflora herb Extract dry concentrate	250 mg
Equivalent: Scutellaria lateriflora (Dry)	1 g
zinc amino acid chelate	10 mg
Equivalent: zinc	2 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
silicon dioxide

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