



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	444670	Neuro Balance
ARTG entry for	Medicine Listed	
Sponsor	The Trustee for Luxton Wellness Trust	
Postal Address	PO Box 6117, Hawthorn West, VIC, 3122 Australia	
ARTG Start Date	27/03/2024	
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 . Neuro Balance

Product Type	Single Medicine Product	Effective Date	27/03/2024
---------------------	-------------------------	-----------------------	------------

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body when dietary intake is inadequate
- Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition
- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing when dietary intake is inadequate
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Maintain/support healthy neuromuscular system/function
- Aid/assist/helps protein synthesis in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral) within normal range when dietary intake is inadequate
- Maintain/support (state vitamin/mineral) within normal range
- Aids/assists the body to cope with environmental stress
- Support healthy stress response in the body
- Traditionally used in Western herbal medicine to soothe/calm nerves
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve symptoms of stress in healthy adults
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
- Decrease/reduce/relieve symptoms of mild anxiety in healthy adults
- Traditionally used in Ayurvedic medicine to nerve tonic
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters when dietary intake is inadequate
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support nervous system health when dietary intake is inadequate

Public Summary



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Traditionally used in Ayurvedic medicine to nervine/support nervous system
 Maintain/support nervous system function
 Maintain/support nervous system function when dietary intake is inadequate
 Support healthy emotional/mood balance in healthy adults
 Traditionally used in Western herbal medicine to decrease/reduce/relieve sleeplessness
 Traditionally used in Western herbal medicine to 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 not imply or refer to chronic fatigue syndrome.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
 Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Product presentation must only refer to mild anxiety.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
------------------	------------------------

Components

1 . Formulation 1

Dosage Form	Powder, oral
Route of Administration	Oral

Visual Identification

Active Ingredients

ascorbic acid	12 mg/g
Bacopa monnieri whole plant Extract dry concentrate	50 mg/g
Equivalent: Bacopa monnieri (Dry)	1 g/g
calcium pantothenate	1.09 mg/g
Equivalent: pantothenic acid	1 mg/g
Crocus sativus stigma Extract dry concentrate	3 mg/g
Equivalent: Crocus sativus (Dry)	9 mg/g
cysteine	6 mg/g
glycine	296.9 mg/g
inositol	12.5 mg/g
magnesium citrate	155.2 mg/g
Equivalent: magnesium	22.5 mg/g
Melissa officinalis leaf Extract dry concentrate	30 mg/g
Equivalent: Melissa officinalis (Dry)	450 mg/g
ornithine	50 mg/g

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

potassium citrate	20.9 mg/g
Equivalent: potassium	8 mg/g
soy phosphatidylserine-enriched soy lecithin powder	15 mg/g
Equivalent: soy phosphatidylserine	7.5 mg/g
taurine	50 mg/g

Other Ingredients (Excipients)

Beta vulgaris
citric acid
colloidal anhydrous silica
Flavour
maltodextrin
Stevia rebaudiana

© 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