



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	380395	Neurenergy
ARTG entry for	Medicine Listed	
Sponsor	Bio-Practica Pty Ltd	
Postal Address	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia	
ARTG Start Date	8/12/2021	
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 . Neurenergy

Product Type	Single Medicine Product	Effective Date	8/12/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition
- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Traditionally used in Eastern European herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support general health and wellbeing
- Maintain/support healthy blood circulation
- Maintain/support blood circulation/flow to the peripheral areas of the body (legs, hands and feet)
- Traditionally used in European herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in European herbal medicine to aids/assists the body to cope with environmental stress
- Helps enhance/improve/promote/increase attention span
- Traditionally used in Ayurvedic medicine to maintain/support mental concentration/focus/clarity
- Maintain/support mental concentration/focus/clarity
- Enhance/improve/promote/increase cognitive performance
- Traditionally used in European herbal medicine to maintain/support cognitive function/mental function
- Enhance/improve/promote/increase mental alertness/wakefulness
- Enhance/improve/promote/increase memory/recall
- Traditionally used in Ayurvedic medicine to nervine/support nervous system

Indication Requirements

- Product presentation must not imply or refer to serious cardiovascular conditions.
- 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 mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record



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Specific Indications

No Specific Indications included on Record

Warnings

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

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Alpinia galanga rhizome Extract dry concentrate	150 mg
Equivalent: Alpinia galanga (Dry)	1.5 g
Bacopa monnieri whole plant Extract dry concentrate standardised	150 mg
Equivalent: Bacopa monnieri (Dry)	3000 mg
Centella asiatica leaf Extract dry concentrate	150 mg
Equivalent: Centella asiatica (Dry)	1.5 g
Ginkgo biloba leaf Extract dry concentrate	60 mg
Equivalent: Ginkgo biloba (Dry)	3 g
Rhodiola rosea root Extract dry concentrate	75 mg
Equivalent: Rhodiola rosea (Dry)	300 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 400
magnesium stearate
maltodextrin
microcrystalline cellulose
povidone
silicon dioxide

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