



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	104361	Mediherb Bacopa Complex (N/F)
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	2/07/2004	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Mediherb Bacopa Complex (N/F)**

Product Type	Single Medicine Product	Effective Date	9/11/2019
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**Permitted Indications**

- 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 Chinese medicine to calm/stabilise/settle/regulate shen
- Relieve feelings of general malaise/general debility
- Maintain/support physical endurance/capacity/stamina
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to cardi tonic/strengthen heart
- Aids/assists the body to cope with environmental stress
- Support healthy stress response in the body
- Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit
- Maintain/support mental endurance/stamina
- Maintain/support cognitive function/mental function in elderly individuals
- Maintain/support cognitive function/mental function In older females
- Maintain/support cognitive function/mental function In older males
- Maintain/support cognitive function/mental function
- Traditionally used in Ayurvedic medicine to brain tonic/Enhance brain health
- Traditionally used in Ayurvedic medicine to nerve tonic
- Traditionally used in Chinese medicine to decrease/reduce/relieve disturbed/restless sleep

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**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.

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.

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

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to serious cardiovascular conditions.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

If symptoms persist, seek the advice of a healthcare professional.

For practitioner dispensing only.

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Bacopa monnieri</b>	<b>75 mg</b>
Equivalent: Bacopa monnieri	3.75 g
Equivalent: bacosides calculated as bacoside A (of Bacopa monnieri)	37.5 mg
<b>Eleutherococcus senticosus</b>	<b>50 mg</b>
Equivalent: Eleutherococcus senticosus	500 mg
Equivalent: syringaresinol diglucosides (of Eleutherococcus senticosus)	400 microgram
<b>Rosemary Oil</b>	<b>10 mg</b>
Equivalent: safrole	100 microgram
<b>Schisandra chinensis</b>	<b>110 mg</b>
Equivalent: Schisandra chinensis	660 mg

**Other Ingredients (Excipients)**

- calcium hydrogen phosphate dihydrate
- colloidal anhydrous silica
- hypromellose
- magnesium stearate
- microcrystalline cellulose
- sodium starch glycollate

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