



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	342375	Mediherb Bacopa Complex
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	26/08/2020	
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 . Mediherb Bacopa Complex

Product Type	Single Medicine Product	Effective Date	29/01/2021
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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

Maintain/support cognitive function/mental function in elderly individuals

Maintain/support cognitive function/mental function In older males

Maintain/support cognitive function/mental function In older females

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

Indication Requirements

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

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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.

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.



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Label statement: If symptoms persist, talk to your health professional.

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.

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

For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Bacopa monnieri whole plant Extract dry concentrate	145 mg
Equivalent: Bacopa monnieri (Dry)	2900 mg
Eleutherococcus senticosus root Extract dry concentrate standardised	50 mg
Equivalent: Eleutherococcus senticosus (Dry)	500 mg
Rosemary Oil	10 mg
Schisandra chinensis fruit Extract dry concentrate	110 mg
Equivalent: Schisandra chinensis (Dry)	660 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

hypromellose

magnesium stearate

maltodextrin

microcrystalline cellulose

sodium starch glycollate

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