



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	231823	KeenMind
ARTG entry for	Medicine Listed	
Sponsor	SFI Australasia	
Postal Address	PO Box 1027, CROWS NEST, NSW, 1585 Australia	
ARTG Start Date	15/12/2014	
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.

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 . KeenMind

Product Type	Single Medicine Product	Effective Date	18/10/2019
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition
- Traditionally used in Ayurvedic medicine to maintain/support cardiovascular system health
- Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
- Relieve irritability
- Soothe/calm nerves
- Decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve nervous tension/unrest
- Decrease/reduce/relieve symptoms of mild anxiety
- Helps enhance/improve/promote/increase attention span
- Decrease/reduce mental/cognitive fatigue
- Maintain/support mental concentration/focus/clarity
- Enhance/improve/promote/increase cognitive performance
- Enhance/improve/promote/increase mental endurance/stamina
- Maintain/support mental endurance/stamina
- Maintain/support cognitive function/mental function
- Maintain/support learning and information processing
- Traditionally used in Ayurvedic medicine to maintain/support learning and information processing

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Enhance/improve/promote learning ability/function
 Traditionally used in Ayurvedic medicine to enhance/improve/promote learning ability/function
 Enhance/improve/promote/increase mental alertness/wakefulness
 Enhance/improve/promote/increase memory/recall
 Maintain/support memory/mental recall
 Enhance/improve/promote/increase short term memory
 Maintain/support general mental wellbeing
 Maintain/support brain function
 Maintain/support brain health
 Traditionally used in Ayurvedic medicine to nerve tonic
 Helps enhance/promote healthy nerve conduction/transmission/neurotransmission

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to serious cardiovascular conditions.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must only refer to mild anxiety.
 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.

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
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

Bacopa monnieri whole plant Extract dry concentrate	160 mg
Equivalent: Bacopa monnieri (Dry)	2.16 g

Other Ingredients (Excipients)

calcium hydrogen phosphate
 chlorophyllin-copper complex
 colloidal anhydrous silica
 hypromellose
 magnesium stearate
 microcrystalline cellulose
 purified talc
 titanium dioxide

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