



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	231823	KeenMind
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	SFI Australasia	
<b>Postal Address</b>	PO Box 1027, CROWS NEST, NSW, 1585 Australia	
<b>ARTG Start Date</b>	15/12/2014	
<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 . 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
- Traditionally used in Ayurvedic medicine to maintain/support learning and information processing
- Maintain/support learning and information processing

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Traditionally used in Ayurvedic medicine to enhance/improve/promote learning ability/function  
 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.  
 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.  
 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**

No Warnings included on Record

**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**                      Capsule, hard  
**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>Bacopa monnieri whole plant Extract dry concentrate</b>	<b>160 mg</b>
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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