



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	328682	METAGENICS BRAHMI TONE
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	16/01/2020	
<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.

The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - National Formulary 27 (USP32-NF27) as in force or existing from time to time. This condition does not apply to powdered or dried leaf.

**Products**

**1 . METAGENICS BRAHMI TONE**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	16/01/2020
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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 adaptogen/Help body adapt to stress
- Decrease/reduce/relieve symptoms of stress
  - Linked indication - Decrease/reduce mental/cognitive fatigue
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress
  - Linked indication - Decrease/reduce mental/cognitive fatigue
  - Linked indication - Enhance/improve/promote/increase cognitive performance
- Decrease/reduce/relieve symptoms of stress
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Ayurvedic medicine to maintain/support mental concentration/focus/clarity
- Traditionally used in Ayurvedic medicine to enhance/improve/promote/increase cognitive performance
- Enhance/improve/promote/increase cognitive performance
- Maintain/support mental endurance/stamina
- Traditionally used in Ayurvedic medicine to maintain/support cognitive function/mental function
- Maintain/support cognitive function/mental function
- Enhance/improve/promote learning ability/function
- Traditionally used in Ayurvedic medicine to enhance/improve/promote/increase memory/recall

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Traditionally used in Ayurvedic medicine to nerve tonic  
 Maintain/support nervous system function  
 Traditionally used in Ayurvedic medicine to maintain/support nervous system function

**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.  
 Product presentation must only refer to mild anxiety.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Contains caffeine [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.  
 Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.  
 Adults only.  
 If symptoms persist consult your healthcare practitioner (or words to that effect).

**Additional Product information**

**Pack Size/Poison information**

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

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>Bacopa monnieri</b>	<b>75 mg</b>
<b>Camellia sinensis</b>	<b>125 mg</b>
<b>Ginkgo biloba leaf Extract dry concentrate</b>	<b>30 mg</b>
Equivalent: Ginkgo biloba (Dry)	1.5 g
<b>tyrosine</b>	<b>500 mg</b>
<b>Withania somnifera root Extract dry concentrate</b>	<b>30 mg</b>
Equivalent: Withania somnifera (Dry)	750 mg

**Other Ingredients (Excipients)**

- calcium hydrogen phosphate dihydrate
- croscarmellose sodium
- hypromellose
- macrogol 400
- magnesium stearate
- microcrystalline cellulose
- silicon dioxide
- sodium starch glycollate type A

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