



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

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

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

Product Type	Single Medicine Product	Effective Date	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
- Enhance/improve/promote/increase cognitive performance
- Traditionally used in Ayurvedic medicine to enhance/improve/promote/increase cognitive performance
- Maintain/support mental endurance/stamina
- Maintain/support cognitive function/mental function
- Traditionally used in Ayurvedic medicine to 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
 Traditionally used in Ayurvedic medicine to maintain/support nervous system function
 Maintain/support nervous system function

Indication Requirements

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

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.
 Adults only.
 If symptoms persist consult your healthcare practitioner (or words to that effect).
 Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.

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	75 mg
Camellia sinensis	125 mg
Ginkgo biloba leaf Extract dry concentrate	30 mg
Equivalent: Ginkgo biloba (Dry)	1.5 g
tyrosine	500 mg
Withania somnifera root Extract dry concentrate	30 mg
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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