



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	370885	MEMORY + COGNITION
ARTG entry for	Medicine Listed	
Sponsor	JSHealth Vitamins Pty Ltd	
Postal Address	14/409 New South Head Road, Double Bay, Sydney, NSW, 2028 Australia	
ARTG Start Date	12/07/2021	
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 . MEMORY + COGNITION

Product Type	Single Medicine Product	Effective Date	20/08/2021
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Permitted Indications

- Maintain/support energy levels
- Maintain/support energy production
- Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate
- Maintain/support general health and wellbeing
- Aid/assist healthy red blood cell production
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Calms the mind
- Soothe/calm nerves
- Decrease/reduce/relieve symptoms of mild anxiety
- Maintain/support cognitive function/mental function
- Maintain/support cognitive function/mental function in elderly individuals
- Maintain/support learning and information processing in elderly individuals
- Enhance/improve/promote/increase memory/recall in elderly individuals
- Maintain/support memory/mental recall
- Maintain/support memory/mental recall in elderly individuals
- Maintain/support general mental wellbeing
- Maintain/support brain function
- Maintain/support brain function in elderly individuals
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support nervous system function

Indication Requirements

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

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



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If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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

Product presentation must not imply or refer to serious cardiovascular conditions.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Product presentation must not imply or refer to serious immunological diseases.

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

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 Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Bacopa monnieri whole plant Extract dry concentrate	150 mg
Equivalent: Bacopa monnieri (Dry)	3 g
choline bitartrate	302.68 mg
Equivalent: choline	125 mg
Ginkgo biloba leaf Extract dry concentrate	60 mg
Equivalent: Ginkgo biloba (Dry)	3 g
Melissa officinalis leaf Extract dry concentrate	150 mg
Equivalent: Melissa officinalis (Dry)	525 mg
pyridoxine hydrochloride	6.08 mg
Equivalent: pyridoxine	5 mg
Schisandra chinensis fruit Extract dry concentrate	80 mg
Equivalent: Schisandra chinensis (Dry)	2 g
tyrosine	100 mg

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- Carnauba Wax
- chlorophyllin-copper complex
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- ethylcellulose
- hypromellose
- macrogol 400
- magnesium stearate
- maltodextrin
- microcrystalline cellulose

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povidone

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