



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	368195	CogniCare
ARTG entry for	Medicine Listed	
Sponsor	Biomedica Nutraceuticals Pty Ltd	
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	4/06/2021	
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 . CogniCare

Product Type	Single Medicine Product	Effective Date	4/06/2021
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support general health and wellbeing

Maintain/support healthy blood circulation

Maintain/support blood circulation/flow to the peripheral areas of the body (legs, hands and feet)

Maintain/support cognitive function/mental function

Maintain/support memory/mental recall

Maintain/support brain health

Maintain/support nervous system health

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.

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

Components

1 . Formulation 1



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Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Bacopa monnieri whole plant Extract dry concentrate standardised	225 mg
Equivalent: Bacopa monnieri (Dry)	4500 mg
d-alpha-tocopheryl acid succinate	8.26 mg
Ginkgo biloba leaf Extract dry concentrate standardised	60 mg
Equivalent: Ginkgo biloba (Dry)	3 g
soy phosphatidylserine-enriched soy lecithin powder	83.33 mg
Equivalent: soy phosphatidylserine	50 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
chlorophyllin-copper complex
colloidal anhydrous silica
hypromellose
purified water
Rice bran

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