



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	230161	Cognition Support
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	5/11/2014	
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.

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 . Cognition Support

Product Type	Single Medicine Product	Effective Date	19/11/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support energy production
- Maintain/support physical endurance/capacity/stamina
- Relieve weariness/tiredness/fatigue/feeling of weakness
- 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 cognitive function/mental function in aging individuals
- Maintain/support learning and information processing in aging individuals
- Maintain/support memory/mental recall in aging individuals
- Maintain/support memory/mental recall

Indication Requirements

- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

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Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

alpha lipoic acid	300 mg
Bacopa monnieri	200 mg
Ginkgo biloba	60 mg
Panax ginseng root Extract dry concentrate standardised	70.83 mg
Equivalent: Panax ginseng (Dry)	212.5 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

Carnauba Wax

chlorophyllin-copper complex

colloidal anhydrous silica

croscarmellose sodium

crospovidone

hypromellose

macrogol 400

magnesium stearate

microcrystalline cellulose

povidone

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