



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	169068	Gincosan
ARTG entry for	Medicine Listed	
Sponsor	SFI Australasia	
Postal Address	PO Box 1027, CROWS NEST, NSW, 1585 Australia	
ARTG Start Date	13/02/2010	
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 . Gincosan

Product Type	Single Medicine Product	Effective Date	18/10/2019
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support physical endurance/capacity/stamina
- Maintain/support healthy blood circulation
- Maintain/support blood circulation/flow to the peripheral areas of the body (legs, hands and feet)
- Decrease/reduce mental/cognitive fatigue
- Maintain/support mental concentration/focus/clarity
- Enhance/improve/promote/increase cognitive performance
- Maintain/support cognitive function/mental function
- Maintain/support learning and information processing
- Enhance/improve/promote/increase mental alertness/wakefulness
- Enhance/improve/promote/increase memory/recall
- Maintain/support memory/mental recall
- Enhance/improve/promote/increase short term memory
- Maintain/support brain function

Indication Requirements

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

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

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

Contains lactose (or words to that effect).

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Ginkgo biloba leaf Extract dry concentrate	60 mg
Equivalent: Ginkgo biloba (Dry)	2.16 g
Panax ginseng root Extract dry concentrate	100 mg
Equivalent: Panax ginseng (Dry)	212.5 mg

Other Ingredients (Excipients)

Gelatin

iron oxide red

iron oxide yellow

magnesium stearate

mannitol

purified water

silicon dioxide

titanium dioxide

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