# 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<br>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

#### 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**

(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].
Contains lactose (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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