Public Summary

Summary for ARTG Entry:	199134 Ginsana
ARTG entry for	Medicine Listed
Sponsor	SFI Australasia
Postal Address	PO Box 1027, CROWS NEST, NSW, 1585 Australia
ARTG Start Date	6/07/2012
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.

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.

Products

1 . Ginsana

Product Type	Single Medicine Product	**Effective Date**	10/06/2020

Permitted Indications

Maintain/support energy levels
Maintain/support energy production
Maintain/support physical endurance/capacity/stamina
Maintain/support vitality
Relieve weariness/tiredness/fatigue/feeling of weakness
Relieve weariness/tiredness/fatigue/feeling of weakness
Maintain/support general health and wellbeing
Maintain/support immune system health
Enhance/improve/promote immune defence/immunity
Helps enhance/improve/promote immune system function
Maintain/support healthy immune system function
Helps stimulate a healthy immune system response
Aids/assists the body to cope with environmental stress
Support healthy body stress recovery
Maintain/support cognitive function/mental function

Indication Requirements

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

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 immunological diseases.

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

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Not recorded	Not recorded	Not recorded	Neither child resistant closure nor restricted flow insert	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

Panax ginseng root Extract dry concentrate	**100 mg**
Equivalent: Panax ginseng (Dry)	212.5 mg

Other Ingredients (Excipients)

chlorophyllin-copper complex
Gelatin
magnesium stearate
mannitol
silicon dioxide
titanium dioxide