



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	94802	KOREAN GINSENG 2500
ARTG entry for	Medicine Listed	
Sponsor	Vitaco Health Australia Pty Ltd	
Postal Address	PO Box 399, NORTH RYDE BC, NSW, 1670 Australia	
ARTG Start Date	10/06/2003	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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 . KOREAN GINSENG 2500

Product Type	Single Medicine Product	Effective Date	7/01/2020
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Permitted Indications

- Traditionally used in Chinese medicine to engender Fluid
- Traditionally used in Chinese medicine to tonify/hourish/strengthen/replenish Qi
- Traditionally used in Chinese medicine to tonify/hourish/strengthen/replenish/fortify/invigorate spleen
- Traditionally used in Chinese medicine to tonify/hourish/strengthen/replenish lungs
- Traditionally used in Chinese medicine to enhance/promote energy levels
- Maintain/support physical endurance/capacity/stamina
- Traditionally used in Chinese medicine to maintain/support vitality
- Relieve weariness/tiredness/fatigue/feeling of weakness in healthy individuals
- Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Chinese medicine to body tonic
- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- Traditionally used in Chinese medicine to decrease/reduce/relieve loss of appetite
- Maintain/support healthy immune system function
- Maintain/support mental concentration/focus/clarity
- Traditionally used in Chinese medicine to maintain/support cognitive function/mental function
- Maintain/support cognitive function/mental function

Indication Requirements

- Product presentation must not imply or refer to disease in any body organ.
- If TCM terminology is used on medicine label, label statement: Talk to a TCM practitioner/health professional if you are unsure if this medicine is right for you.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to eating disorders.

Standard Indications

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No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Seek professional advice before long term use.

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

Panax ginseng root Extract dry concentrate standardised	250 mg
Equivalent: Panax ginseng (Dry)	2.5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
Gelatin
magnesium stearate
microcrystalline cellulose
purified water
sodium lauryl sulfate

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