



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	346958	NUTRA-LIFE GUARANA GINSENG 4000
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	2/11/2020	
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.

Products

1 . NUTRA-LIFE GUARANA GINSENG 4000

Product Type	Single Medicine Product	Effective Date	2/11/2020
---------------------	-------------------------	-----------------------	-----------

Permitted Indications

- Traditionally used in Western herbal medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Western herbal medicine to body tonic
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to astringent/tightens tissues
- Traditionally used in Western herbal medicine to decrease/reduce mental/cognitive fatigue
- Traditionally used in Western herbal medicine to decrease/reduce/relieve headache symptoms
- Traditionally used in Western herbal medicine to decrease/reduce/relieve mild migraine symptoms
- Traditionally used in Western herbal medicine to nerve tonic
- Traditionally used in Western herbal medicine to nerve stimulant/enhance nerve function
- Traditionally used in Western herbal medicine to nervine/support nervous system

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

- Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.
- Adults only.
- Contains caffeine [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.



Australian Government
Department of Health
Therapeutic Goods Administration

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

Eleutherococcus senticosus root Extract dry concentrate	66.67 mg
Equivalent: Eleutherococcus senticosus (Dry)	1 g
Panax ginseng root Extract dry concentrate	100 mg
Equivalent: Panax ginseng (Dry)	1 g
Paullinia cupana seed Extract dry concentrate standardised	200 mg
Equivalent: Paullinia cupana (Dry)	2 g

Other Ingredients (Excipients)

calcium hydrogen phosphate

colloidal anhydrous silica

Gelatin

magnesium stearate

maltodextrin

microcrystalline cellulose

purified water

sodium lauryl sulfate

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary