



Australian Government

Department of Health, Disability and Ageing  
Therapeutic Goods Administration

Public Summary

<b>Summary for ARTG Entry:</b>	395534	Energy and Stress Support
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Whole Health Studio	
<b>Postal Address</b>	4 Glenelg Avenue, Mermaid Beach, QLD, 4218 Australia	
<b>ARTG Start Date</b>	6/09/2022	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Energy and Stress Support**

Product Type	Single Medicine Product	Effective Date	31/10/2023
--------------	-------------------------	----------------	------------

**Permitted Indications**

- Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition
- Traditionally used in Ayurvedic medicine to kapha & Vata roga/relieve Kapaha & Vata disturbance
- Traditionally used in Ayurvedic medicine to balya/improve body strength
- Traditionally used in Ayurvedic medicine to vrishya/aphrodisiac/Increase in virility in healthy males
- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Traditionally used in Ayurvedic medicine to balance aggravated Vata
- Traditionally used in Chinese medicine to tonify/nourish/strengthen/replenish Qi
- Traditionally used in Chinese medicine to invigorate/nourish/tonify/strengthen/replenish heart-qi
- Maintain/support energy levels
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence
- Maintain/support physical endurance/capacity/stamina
- Traditionally used in Chinese medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Ayurvedic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Chinese medicine to maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to anti-inflammatory/relieve inflammation
- Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
- Traditionally used in Ayurvedic medicine to support healthy body stress recovery
- Traditionally used in Ayurvedic medicine to support healthy stress response in the body
- Traditionally used in Chinese medicine to calm/soothe/nourish/balance spirit
- Maintain/support mental concentration/focus/clarity
- Maintain/support cognitive function/mental function
- Traditionally used in Ayurvedic medicine to nervine/support nervous system
- Traditionally used in Ayurvedic medicine to soporific/induces sleep
- Traditionally used in Chinese medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Ayurvedic medicine to aphrodisiac/Enhance/improve/promote healthy libido
- Traditionally used in Ayurvedic medicine to maintain/support healthy sexual function in healthy males

Public Summary



Australian Government

Department of Health, Disability and Ageing  
Therapeutic Goods Administration

Public Summary

**Indication Requirements**

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

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

Label statement: If symptoms persist, talk to your health professional.

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

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.

Product presentation must not imply or refer to heart disease.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Do not take while on warfarin therapy without medical advice.

**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**

<b>Eleutherococcus senticosus root Extract dry concentrate</b>	<b>66.67 mg</b>
Equivalent: Eleutherococcus senticosus (Dry)	1 g
<b>Ganoderma lucidum fruiting body Extract dry concentrate</b>	<b>37.5 mg</b>
Equivalent: Ganoderma lucidum (Dry)	750 mg
<b>Grifola frondosa fruiting body Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Grifola frondosa (Dry)	500 mg
<b>Lentinula edodes fruiting body Extract dry concentrate</b>	<b>50 mg</b>
Equivalent: Lentinula edodes (Dry)	500 mg
<b>Withania somnifera root Extract dry concentrate</b>	<b>200 mg</b>
Equivalent: Withania somnifera (Dry)	4 g

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
dextrin  
hypromellose  
magnesium stearate  
maltodextrin  
microcrystalline cellulose  
purified water

© 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>.