



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	214216	Stress Ease
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	5/09/2013	
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 . Stress Ease

Product Type	Single Medicine Product	Effective Date	27/07/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Traditionally used in Ayurvedic medicine to medhya/brain tonic/improve memory and cognition
- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Aids/assists with recovery from illness/convalescence
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility
- Maintain/support energy production
- Traditionally used in Western herbal medicine to enhance/promote/physical endurance/capacity/stamina
- Maintain/support physical endurance/capacity/stamina
- Traditionally used in Ayurvedic medicine to helps enhance/promote/increase vitality
- Traditionally used in Ayurvedic medicine to maintain/support vitality
- Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support adrenal gland health
- Traditionally used in Western herbal medicine to maintain/support healthy adrenal gland function
- Traditionally used in Western herbal medicine to helps enhance/improve/promote/increase physical/exercise performance
- Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Ayurvedic medicine to support healthy stress response in the body
- Support healthy stress response in the body
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
- Maintain/support mental concentration/focus/clarity
- Traditionally used in Western herbal medicine to enhance/improve/promote/increase mental endurance/stamina
- Maintain/support mental endurance/stamina

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Traditionally used in Western herbal medicine to maintain/support mental endurance/stamina
 Maintain/support cognitive function/mental function
 Maintain/support memory/mental recall
 Traditionally used in Ayurvedic medicine to nervine/support nervous system
 Traditionally used in Ayurvedic medicine to enhance/improve/promote/increase sleep quality/deep sleep

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 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.
 Label statement: If symptoms persist, talk to your health professional.
 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.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 Product presentation must not imply or refer to any adrenal related diseases.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

Glycyrrhiza glabra rhizome Extract dry concentrate	125 mg
Equivalent: Glycyrrhiza glabra (Dry)	1 g
Rehmannia glutinosa root Extract dry concentrate	166.67 mg
Equivalent: Rehmannia glutinosa (Dry)	1 g
Rhodiola rosea root Extract dry concentrate standardised	100 mg
Equivalent: Rhodiola rosea (Dry)	400 mg
tyrosine	150 mg
Withania somnifera root Extract dry concentrate standardised	150 mg
Equivalent: Withania somnifera (Dry)	1.5 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
 Carnuba Wax
 colloidal anhydrous silica
 croscarmellose sodium
 crospovidone
 hypromellose
 macrogol 400
 magnesium stearate
 microcrystalline cellulose
 povidone

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