



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	385335	AdrenaSense
ARTG entry for	Medicine Listed	
Sponsor	Factors Group Australia Pty Ltd	
Postal Address	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
ARTG Start Date	9/03/2022	
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 . AdrenaSense

Product Type	Single Medicine Product	Effective Date	6/05/2022
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support energy levels
- Traditionally used in Western herbal medicine to maintain/support energy levels
- Maintain/support physical endurance/capacity/stamina
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- Helps enhance/promote general health and wellbeing
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to enhance/improve/promote immune defence/immunity
- Traditionally used in Chinese medicine to helps enhance/improve/promote immune system function
- Traditionally used in Chinese medicine to maintain/support healthy immune system function
- Traditionally used in Western herbal medicine to adaptogen/Help body adapt to stress
- Traditionally used in Western herbal medicine to enhance/promote body adaptation to stress
- Traditionally used in Western herbal medicine to support healthy stress response in the body
- Traditionally used in Western herbal medicine to soothe/calm nerves
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve symptoms of stress
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nervous tension/unrest
- Decrease/reduce mental/cognitive fatigue
- Maintain/support mental concentration/focus/clarity
- Enhance/improve/promote/increase cognitive performance
- Traditionally used in Western herbal medicine to maintain/support mental endurance/stamina
- Maintain/support mental endurance/stamina
- Traditionally used in Western herbal medicine to maintain/support cognitive function/mental function
- Maintain/support cognitive function/mental function
- Traditionally used in Western herbal medicine to enhance/improve/promote/increase memory/recall

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Traditionally used in Western herbal medicine to maintain/support brain function
 Traditionally used in Western herbal medicine to maintain/support nervous system health
 Traditionally used in Western herbal medicine to calmative/nervous system relaxant
 Traditionally used in Western herbal medicine to support healthy emotional/mood balance
 Support healthy emotional/mood balance

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 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

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

Cucumis melo fruit Juice concentrate	5 mg	
Equivalent: Cucumis melo (Fresh)		185 mg
Eleutherococcus senticosus root Extract dry concentrate	100 mg	
Equivalent: Eleutherococcus senticosus (Dry)		1.5 g
Ganoderma lucidum fruiting body Extract dry concentrate	50 mg	
Equivalent: Ganoderma lucidum (Dry)		1.5 g
Rhodiola rosea root Extract dry concentrate	100 mg	
Equivalent: Rhodiola rosea (Dry)		1 g
Schisandra chinensis fruit Extract dry concentrate	100 mg	
Equivalent: Schisandra chinensis (Dry)		2 g
Withania somnifera root Extract dry concentrate	300 mg	
Equivalent: Withania somnifera (Dry)		3 g

Other Ingredients (Excipients)

hypromellose
 magnesium stearate
 maltodextrin
 microcrystalline cellulose
 Shellac
 silicon dioxide

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written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

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