



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	299719	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	16/02/2018	
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	24/02/2021
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Permitted Indications

Maintain/support energy levels
Traditionally used in Western herbal medicine to maintain/support energy levels
Maintain/support energy production
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 adaptogen/Help body adapt to stress
Enhance/promote body adaptation to stress
Maintain/support mental concentration/focus/clarity
Enhance/improve/promote/increase cognitive performance
Maintain/support cognitive function/mental function
Maintain/support brain function

Indication Requirements

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.

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 mental illnesses, disorders or conditions.

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).

Do not use if pregnant or likely to become pregnant (or words to that effect)



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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

Bacopa monnieri leaf Extract dry concentrate	100 mg
Equivalent: Bacopa monnieri (Dry)	2 g
Eleutherococcus senticosus root Extract dry concentrate standardised	100 mg
Equivalent: Eleutherococcus senticosus (Dry)	1.5 g
Rhodiola rosea root Extract dry concentrate standardised	100 mg
Equivalent: Rhodiola rosea (Dry)	1000 mg
Schisandra chinensis fruit Extract dry concentrate standardised	80 mg
Equivalent: Schisandra chinensis (Dry)	1.6 g
Withania somnifera root Extract dry concentrate standardised	80 mg
Equivalent: Withania somnifera (Dry)	400 mg

Other Ingredients (Excipients)

hypromellose

magnesium stearate

maltodextrin

microcrystalline cellulose

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