



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	158604	METAGENICS ADRENOTONE
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	20/01/2009	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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 . METAGENICS ADRENOTONE

Product Type	Single Medicine Product	Effective Date	2/07/2020
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Permitted Indications

- Maintain/support physical endurance/capacity/stamina
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to maintain/support adrenal gland health
- Traditionally used in Ayurvedic medicine to maintain/support healthy adrenal gland function
- Support healthy stress response in the body
- Traditionally used in Ayurvedic medicine to soothe/calm nerves
- Decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve symptoms of stress
 - Linked indication - Relieve weariness/tiredness/fatigue/feeling of weakness
 - Linked indication - Decrease/reduce mental/cognitive fatigue
- Decrease/reduce mental/cognitive fatigue
- Traditionally used in Ayurvedic medicine to nervine/support nervous system

Indication Requirements

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

Additional Product information

Pack Size/Poison information



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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Eleutherococcus senticosus root Extract dry concentrate	100 mg
Equivalent: Eleutherococcus senticosus (Dry)	2.8 g
Glycyrrhiza glabra root Extract dry concentrate	66.7 mg
Equivalent: Glycyrrhiza glabra (Dry)	1000 mg
Panax ginseng root Extract dry concentrate	62.5 mg
Equivalent: Panax ginseng (Dry)	281.3 mg
Rhodiola rosea root Extract dry concentrate	102 mg
Equivalent: Rhodiola rosea (Dry)	1.02 g
tyrosine	500 mg
Withania somnifera root Extract dry concentrate	152 mg
Equivalent: Withania somnifera (Dry)	3.8 g

Other Ingredients (Excipients)

carrageenan

croscarmellose sodium

macrogol 8000

microcrystalline cellulose

powdered cellulose

silicon dioxide

stearic acid

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