



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	214065	Adrenoplex
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	2/09/2013	
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.

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 . Adrenoplex

Product Type	Single Medicine Product	Effective Date	7/10/2021
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Permitted Indications

- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Traditionally used in Ayurvedic medicine to maintain/support energy levels
- Maintain/support energy levels
- Traditionally used in Western herbal medicine to maintain/support energy levels
- Maintain/support energy production
- 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
- 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
- Aids/assists the body to cope with environmental stress
- Enhance/promote body adaptation to stress
- Support healthy stress response in the body
- Traditionally used in Ayurvedic medicine to soothe/calm nerves
- Decrease/reduce/relieve symptoms of stress
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve nervous tension/unrest
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of mild anxiety
- Decrease/reduce/relieve symptoms of mild anxiety
- Maintain/support mental endurance/stamina
- Maintain/support brain function
- Aid/assist/helps synthesis of neurotransmitters
- Traditionally used in Ayurvedic medicine to calmative/nervous system relaxant
- Traditionally used in Ayurvedic medicine to nervine/support nervous system
- Maintain/support nervous system function
- Support healthy emotional/mood balance

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Traditionally used in Ayurvedic medicine to maintains/supports refreshing sleep
 Maintains/supports refreshing sleep
 Traditionally used in Ayurvedic medicine to maintain/support healthy sleeping patterns

Indication Requirements

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

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Label statement: If symptoms persist, talk to your health professional.

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.

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains lactose (or words to that effect).
 Phenylketonurics are warned that this product contains phenylalanine (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

calcium folinate	69.45 microgram
Equivalent: folic acid	50 microgram
calcium pantothenate	54.58 mg
Equivalent: calcium	4.58 mg
Equivalent: pantothenic acid	50 mg
cyanocobalamin	5 microgram
Eleutherococcus senticosus root Extract dry concentrate standardised	116.67 mg
Equivalent: Eleutherococcus senticosus (Dry)	1.75 g
Ganoderma lucidum fruiting body Extract dry concentrate	3.75 mg
Equivalent: Ganoderma lucidum (Dry)	75 mg
nicotinamide	15 mg
nicotinic acid	5 mg
Panax ginseng root Extract dry concentrate standardised	18 mg
Equivalent: Panax ginseng (Dry)	180 mg
Panax quinquefolius root Extract dry concentrate standardised	12 mg
Equivalent: Panax quinquefolius (Dry)	120 mg
phenylalanine	75 mg
pyridoxal 5-phosphate monohydrate	6.74 mg
Equivalent: pyridoxine	4.3 mg
tyrosine	75 mg

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Withania somnifera root Extract dry concentrate	150 mg
Equivalent: Withania somnifera (Dry)	1.875 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
croscarmellose sodium
crospovidone
Gelatin
magnesium stearate
mannitol
microcrystalline cellulose
povidone
purified water

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