



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	214065	Adrenoplex
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	2/09/2013	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	7/10/2021
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**Permitted Indications**

- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Maintain/support energy levels
- Traditionally used in Western herbal medicine to maintain/support energy levels
- Traditionally used in Ayurvedic medicine to maintain/support energy levels
- Maintain/support energy production
- Maintain/support physical endurance/capacity/stamina
- Traditionally used in Western herbal medicine to relieve weariness/tiredness/fatigue/feeling of weakness
- 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
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress
- Decrease/reduce/relieve symptoms of stress
- Traditionally used in Ayurvedic medicine to decrease/reduce/relieve nervous tension/unrest
- Decrease/reduce/relieve symptoms of mild anxiety
- Traditionally used in Ayurvedic medicine to 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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Maintains/supports refreshing sleep  
 Traditionally used in Ayurvedic medicine to 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 mental illnesses, disorders or conditions.  
 Label statement: If symptoms persist, talk to your health professional.  
 Product presentation must not imply or refer to chronic fatigue syndrome.  
 Product presentation must only refer to mild anxiety.  
 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.  
 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.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Capsule, hard
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

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

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<b>Withania somnifera root Extract dry concentrate</b>	<b>150 mg</b>
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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