



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		273036	AdrenoPS
ARTG entry for	Medicine Listed		
Sponsor	FIT-BioCeuticals Pty Ltd		
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia		
ARTG Start Date	17/03/2016		
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 . AdrenoPS

Product Type	Single Medicine Product	Effective Date	30/05/2023
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Permitted Indications

Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
Maintain/support energy levels
Traditionally used in Ayurvedic medicine to maintain/support energy levels
Maintain/support energy production
Relieve weariness/tiredness/fatigue/feeling of weakness
Helps enhance/promote general health and wellbeing
Traditionally used in Western herbal medicine to maintain/support healthy adrenal gland function
Traditionally used in Ayurvedic medicine to maintain/support healthy adrenal gland function
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
Enhance/promote body adaptation to stress
Support healthy stress response in the body
Decrease/reduce/relieve symptoms of stress in pre-menopausal women
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
Aid/assist/helps synthesis of neurotransmitters
Traditionally used in Ayurvedic medicine to nervine/support nervous system
Maintain/support nervous system function
Support healthy emotional/mood balance
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
Maintain/support healthy sleeping patterns



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Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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.

Product presentation must not imply or refer to any adrenal related diseases.

Product presentation must only refer to mild anxiety.

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.

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

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
[Contains vitamin B6].

Contains lactose (or words to that effect).

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

calcium pantothenate	27.29 mg
Equivalent: calcium	2.29 mg
Equivalent: pantothenic acid	25 mg
Glycyrrhiza glabra root Extract dry concentrate standardised	250 mg
Equivalent: Glycyrrhiza glabra (Dry)	4.375 g
Magnolia officinalis stem bark Extract dry concentrate standardised	51.5625 mg
Equivalent: Magnolia officinalis (Dry)	515.625 mg
Equivalent: honokiol (of Magnolia officinalis) ()	2.8125 mg
Phellodendron amurense stem bark Extract dry concentrate standardised	16.875 mg
Equivalent: Phellodendron amurense (Dry)	185.625 mg
Equivalent: berberine ()	.1875 mg
pyridoxal 5-phosphate monohydrate	7.84 mg
Equivalent: pyridoxine	5 mg
soy phosphatidylserine-enriched soy lecithin powder	50 mg
Equivalent: soy phosphatidylserine	10 mg
Withania somnifera root Extract dry concentrate	150 mg
Equivalent: Withania somnifera (Dry)	1.875 g

Other Ingredients (Excipients)

Carnauba Wax
chlorophyllin-copper complex



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colloidal anhydrous silica
croscarmellose sodium
crospovidone
dextrin
high amylose maize starch
hypromellose
macrogol 8000
magnesium stearate
maize starch
microcrystalline cellulose
povidone
silicon dioxide

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