



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	288713	Eagle Adreno Restore Plus Tablets
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	9/05/2017	
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 . Eagle Adreno Restore Plus Tablets

Product Type	Single Medicine Product	Effective Date	24/01/2022
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Traditionally used in Ayurvedic medicine to balance Vata
- Traditionally used in Ayurvedic medicine to balance aggravated Vata
- Traditionally used in Ayurvedic medicine to enhance/promote energy levels
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence
- Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence in elderly individuals
- Traditionally used in Ayurvedic medicine to relieve feelings of general malaise/general debility
- Relieve feelings of general malaise/general debility
- Maintain/support physical endurance/capacity/stamina
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Traditionally used in Ayurvedic medicine to longevity tonic
- Traditionally used in Ayurvedic medicine to helps enhance/promote general health and wellbeing
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support adrenal gland health
- Traditionally used in Western herbal medicine to maintain/support healthy adrenal gland function
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral) within normal range
- Aids/assists the body to cope with environmental stress
- Support healthy stress response in the body
- Traditionally used in Ayurvedic medicine to calms the mind
- Traditionally used in Ayurvedic medicine to soothe/calm nerves
- Maintain/support mental endurance/stamina

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Traditionally used in Ayurvedic medicine to maintain/support cognitive function/mental function
 Traditionally used in Ayurvedic medicine to maintain/support memory/mental recall
 Traditionally used in Ayurvedic medicine to nerve tonic
 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
 Traditionally used in Ayurvedic medicine to soporific/induces sleep
 Traditionally used in Ayurvedic medicine to decrease/reduce/relieve sleeplessness

Indication Requirements

Product presentation must not imply or refer to chronic fatigue syndrome.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to any adrenal related diseases.
 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.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to serious immunological diseases.
 If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
 Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist, seek the advice of a healthcare professional.
 WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).
 WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].
 For practitioner dispensing only.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

ascorbic acid	75 mg
calcium pantothenate	54.58 mg
Equivalent: calcium	4.58 mg
Equivalent: pantothenic acid	50 mg
d-alpha-tocopheryl acid succinate	74.38 mg
Eleutherococcus senticosus root Extract dry concentrate standardised	66.67 mg
Equivalent: Eleutherococcus senticosus (Dry)	1 g
Glycyrrhiza glabra root Extract dry concentrate standardised	55 mg
Equivalent: Glycyrrhiza glabra (Dry)	962.5 mg
nicotinamide	25 mg

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pyridoxal 5-phosphate monohydrate	18.81 mg
Equivalent: pyridoxine	12 mg
Withania somnifera root Extract dry concentrate standardised	300 mg
Equivalent: Withania somnifera (Dry)	3.75 g
zinc citrate dihydrate	31.15 mg
Equivalent: zinc	10 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
dextrin
ethylcellulose
hypromellose
macrogol 8000
magnesium stearate
microcrystalline cellulose
povidone

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