#### **Australian Government**

# Department of Health, Disability and Ageing

Therapeutic Goods Administration

### **Public Summary**

Summary for ARTG Entry: 288713 Eagle Adreno Restore Plus Tablets

ARTG entry for Medicine Listed

Integria Healthcare Australia Pty Ltd Sponsor

Postal Address PO Box 4854, EIGHT MILE PLAINS, QLD, 4113

9/05/2017 ARTG Start Date **Product Category** Medicine Status Active

Listed Medicines Approval Area

#### 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** Effective Date 19/08/2025 Single Medicine Product

# **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

Relieve feelings of general malaise/general debility

Traditionally used in Ayurvedic medicine to 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**

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.

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: [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).

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

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).

#### Standard Indications

No Standard Indications included on Record

### **Specific Indications**

No Specific Indications included on Record

#### Warnings

For practitioner dispensing only.

If symptoms persist, seek the advice of a healthcare professional.

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin R6]

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).

# Additional Product information

## Pack Size/Poison information

Pack Size Poison Schedule

## Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Ora

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
Equivalent: pyridoxine
12 mg
Withania somnifera root Extract dry concentrate standardised
Equivalent: Withania somnifera (Dry)
3.75 g
zinc citrate dihydrate
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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