



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

## Public Summary

<b>Summary for ARTG Entry:</b>	288713	Eagle Adreno Restore Plus Tablets
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	9/05/2017	
<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 . 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 in elderly individuals  
Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence  
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**

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

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].  
 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).  
 For practitioner dispensing only.  
 If symptoms persist, seek the advice of a healthcare professional.

**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**

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

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