

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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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	9/05/2017
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Warnings

If symptoms persist consult your healthcare practitioner (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.

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).

Standard Indications

Aids, assists or helps in the maintenance or improvement of general well-being.

Non-vitamin active ingredients may improve stress adaptation.

Prevention/treatment of vitamin [XX] and/or mineral [YY] and/or nutritional deficiencies (This indication is not be to used for the treatment of iron deficiency conditions).

Aids, assists or helps in the improvement of general well-being.

Aids, assists or helps in the maintenance of general well-being

Beneficial during times of stress. [Warning S required]

Specific Indications

(Withania root is) Traditionally used in Ayurveda as Rasayana / a rejuvenative tonic / adaptogen.

(Withania root is) Traditionally used in Ayurveda to rejuvenate the body / to re-vitalise the body / promote good health.

(Withania root is) Traditionally used in Ayurveda to support longevity.

(Withania root is) Traditionally used in Ayurveda to boost energy.

(Withania root is) Traditionally used in Ayurveda to relieve general debility, especially during convalescence or old age.

(Withania root is) Traditionally used in Ayurveda as a tonic for the elderly.

(Withania root is) Used in Ayurveda as a sedative and to aid sleep.

(Withania root is) Traditionally used in Ayurveda as a sleep aid.

(Withania root is) Traditionally used in Ayurveda to balance aggravated Vata (nervine tonic, sedative).

(Withania root is) Used in Ayurveda to relieve nervous tension.

(Withania root is) Traditionally used in Ayurveda to support memory.

(Siberian ginseng root) Helps support /improves stress adaptation, supporting the body's resistance towards stress.

(Siberian ginseng root) Helps to temporary relieve symptoms of stress (such as mild / temporary mental fatigue and sensation of weakness).

Helps improve/promote/enhance stress adaptation

(Siberian ginseng root) Helps to improve mental and physical performance when exhausted.
 (Siberian ginseng root) May support mental and physical capacity including mild / temporary weakness, exhaustion and fatigue.
 (Siberian ginseng root is) Used as an adaptogen to help improve mental and/or physical performance.
 Helps enhance/improve/promote/increase physical and mental responses in states of tiredness/fatigue
 Helps maintain/support healthy mental/physical performance
 (Siberian ginseng root) May provide support during times of stress associated with mild / temporary fatigue and declining capacity for work and concentration.
 (Siberian ginseng root is) Used in Herbal Medicine as a tonic to relieve general mild debility and to aid convalescence.
 (Siberian ginseng root) May support the body during convalescence.
 Licorice root is used in traditional Western herbal medicine as a tonic to support adrenal gland function.
 Licorice root is used in traditional Western herbal medicine as an adrenal tonic.
 (Vitamins B5, B6, and C) May help to support healthy adrenal function.
 Provides Vitamins B5, B6, and C, which are important nutrients to support healthy adrenal function.
 B vitamins and vitamin C are needed for healthy adrenal gland function and may support our ability to adequately respond to stress.
 Vitamin C is required for the synthesis of adrenal hormones (catecholamines), such as adrenalin and noradrenalin.
 Helps maintain/support healthy adrenal function
 Helps maintain/support general health and well-being
 For the maintenance of good health.
 For vitamin (B3, B5, B6, and C) supplementation
 For vitamin [B1, B2, B3, B5, B6, B12, biotin, C, E] and/or mineral [zinc] and/or nutritional deficiencies.
 For vitamin [B3, B5, B6, C, and E] deficiency when dietary intake is inadequate
 For mineral (Zinc) supplementation
 May assist in mineral [zinc] deficiency when dietary intake is inadequate
 (Vitamin C, Vitamin E and Zinc) Support(s) a healthy immune system.
 Combines Vitamin C, Vitamin E and Zinc for antioxidant and immune support.
 Provides antioxidants (Vitamin C and E).
 Supports a healthy immune system / Helps maintain immune function.
 Helps immune cellular response in healthy individuals
 Helps maintain/support healthy immune system function
 Helps maintain/support healthy immune regulation
 KSM-66 (Ashwagandha) is a clinically trialled extract shown to improve the stress response, mild anxiety and support healthy cortisol levels in healthy individuals.
 KSM-66 (Ashwagandha) has shown to / may help to relieve nervous tension / Helps to support nervous system function.
 - (Vitamins B5, B6, and C) May help to support healthy adrenal function.
 - Provides Vitamins B5, B6, and C, which are important nutrients to support healthy adrenal function.
 - Vitamin C is required for the synthesis of adrenal hormones (catecholamines), such as adrenalin and noradrenalin.
 - Helps maintain/support healthy adrenal function
 - Supports a healthy immune system / Helps maintain immune function.
 - Helps maintain/support healthy immune system function
 - Helps maintain/support healthy immune regulation
 Provides the standardised Withania (Ashwagandha) root extract KSM-66 at the clinically trialled dose of 300 mg twice daily.

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	
Ascorbic acid	75 mg
Calcium pantothenate	54.58 mg
d-alpha-Tocopheryl acid succinate	74.38 mg
Eleutherococcus senticosus	66.67 mg
Equivalent: Eleutherococcus senticosus (Dry)	1 g
Glycyrrhiza glabra	55 mg
Equivalent: Glycyrrhiza glabra (Dry)	962.5 mg
Nicotinamide	25 mg
pyridoxal 5-phosphate monohydrate	18.81 mg
Withania somnifera	300 mg
Equivalent: Withania somnifera (Dry)	3.75 g
zinc citrate dihydrate	31.15 mg

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