



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 371013 ADRENAL

ARTG entry for Medicine Listed
Sponsor Switch Nutrition
Postal Address PO Box 787, Maroochydore, QLD, 4558
Australia
ARTG Start Date 14/07/2021
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 . ADRENAL

Product Type Single Medicine Product **Effective Date** 24/08/2022

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support collagen formation
Maintain/support natural liver cleansing/detoxification processes
Traditionally used in Ayurvedic medicine to aids/assists with recovery from illness/convalescence
Maintain/support energy production
Traditionally used in Ayurvedic medicine to relieve weariness/tiredness/fatigue/feeling of weakness in healthy elderly individuals
Traditionally used in Ayurvedic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
Maintain/support healthy eye function
Maintain/support eye health
Maintain/support healthy growth and development
Maintain/support general health and wellbeing
Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
Maintain/support healthy teeth
Maintain/support connective tissue health
Aid/assist/helps connective tissue production/formation
Maintain/support bone health
Help maintain/support bone mineralisation
Helps maintain/support joint cartilage health
Aid/assist healthy red blood cell production
Maintain/support red blood cell health
Maintain/support blood health
Helps maintain/support haemoglobin formation/synthesis
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support heart health
Maintain/support blood capillary health



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Traditionally used in Ayurvedic medicine to maintain/support adrenal gland health
Traditionally used in Ayurvedic medicine to maintain/support healthy adrenal gland function
Maintain/support healthy thyroid gland function
Maintain/support healthy thyroid hormones
Aid/assist thyroid hormone production
Maintain/support smell sensation
Maintain/support taste sensation
Maintain/support bile production
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support immune system to fight illness
Maintain/support muscle health
Maintain/support muscle function
Helps decrease/reduce homocysteine levels in healthy individuals
Aid/assist/helps protein synthesis in the body
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral) within normal range
Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
Support healthy stress response in the body
Traditionally used in Ayurvedic medicine to decrease/reduce/relieve symptoms of stress
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 maintain/support general mental wellbeing
Maintain/support neuromuscular function
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Traditionally used in Ayurvedic medicine to maintain/support nervous system health
Traditionally used in Ayurvedic medicine to maintain/support nervous system function
Maintain/support nervous system function
Traditionally used in Ayurvedic medicine to support healthy emotional/mood balance
Maintain/support female reproductive system health
Maintain/support/regulate healthy menstrual cycle
Maintain/support reproductive system health
Maintain/support healthy reproductive hormones
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support wound healing in healthy individuals
Maintain/support skin repair/healing/regeneration in healthy individuals

Indication Requirements

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).

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to drugs/alcohol.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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



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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: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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 not imply or refer to infertility.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

Product presentation must not imply or refer to hormone imbalances.

Product presentation must only refer to detoxification in relation to natural body processes.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	20 mg
magnesium glycinate dihydrate	701.76 mg
Equivalent: magnesium	80 mg
pyridoxal 5-phosphate monohydrate	3.92 mg
Equivalent: pyridoxine	2.5 mg
Withania somnifera root Extract dry concentrate	75 mg
Equivalent: Withania somnifera (Dry)	937.5 mg
zinc amino acid chelate	15 mg
Equivalent: zinc	3 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
edetic acid
gellan gum
hypromellose
magnesium stearate
microcrystalline cellulose
potable water
potassium acetate

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