



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	299404	AdRestore
ARTG entry for	Medicine Listed	
Sponsor	Biomedica Nutraceuticals Pty Ltd	
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	7/02/2018	
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 . AdRestore

Product Type	Single Medicine Product	Effective Date	4/05/2021
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support energy levels
Maintain/support energy production
Relieve weariness/tiredness/fatigue/feeling of weakness
Maintain/support general health and wellbeing
Maintain/support immune system health
Maintain/support healthy immune system function
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Aids/assists the body to cope with environmental stress
Enhance/promote body adaptation to stress
Support healthy body stress recovery
Support healthy stress response in the body
Decrease/reduce/relieve symptoms of stress
Maintain/support mental concentration/focus/clarity
Maintain/support nervous system health
Maintain/support nervous system function

Indication Requirements

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

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

Label statement: If symptoms persist, talk to your health professional.

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

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).

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.



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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

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	100 mg
calcium pantothenate	150 mg
Equivalent: pantothenic acid	137.4 mg
Eleutherococcus senticosus root and rhizome Extract dry concentrate	100 mg
Equivalent: Eleutherococcus senticosus (Dry)	1.5 g
Rehmannia glutinosa root Extract dry concentrate	200 mg
Equivalent: Rehmannia glutinosa (Dry)	2 g
Withania somnifera root Extract dry concentrate	166.67 mg
Equivalent: Withania somnifera (Dry)	2 g
zinc citrate dihydrate	31.15 mg
Equivalent: zinc	10 mg

Other Ingredients (Excipients)

chlorophyllin-copper complex
colloidal anhydrous silica
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
purified water

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