



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

## Public Summary

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	4/05/2021
---------------------	-------------------------	-----------------------	-----------

### 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.



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

**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**

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

**Other Ingredients (Excipients)**

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

# Public Summary

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.