



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	337658	BioActivated B
<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>	10/06/2020	
<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 . BioActivated B**

Product Type	Single Medicine Product	Effective Date	8/06/2022
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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 production
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support gum health
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Helps maintain/support joint cartilage health
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Helps maintain/support healthy cholesterol
- Helps maintain/support healthy blood sugar/glucose
- Maintain/support cardiovascular system health
- Maintain/support heart health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- 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
- Support healthy stress response in the body
- Maintain/support cognitive function/mental function
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health



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

Maintain/support nervous system function  
 Support healthy emotional/mood balance  
 Maintain/support wound healing

**Indication Requirements**

Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
 Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range  
 Product presentation must not imply or refer to serious cardiovascular conditions.  
 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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.  
 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.  
 Label statement: If symptoms persist, talk to your health professional.  
 Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.  
 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).

**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].

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Capsule, hard
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>100 mg</b>
<b>Biotin</b>	<b>500 microgram</b>
<b>calcium folinate</b>	<b>540 microgram</b>
Equivalent: folic acid	500 microgram
<b>calcium pantothenate</b>	<b>50 mg</b>
Equivalent: pantothenic acid	45.8 mg
<b>choline bitartrate</b>	<b>75 mg</b>
<b>hydroxocobalamin</b>	<b>100 microgram</b>
<b>inositol</b>	<b>75 mg</b>
<b>mecobalamin (co-methylcobalamin)</b>	<b>400 microgram</b>
<b>nicotinamide</b>	<b>100 mg</b>
<b>pyridoxal 5-phosphate monohydrate</b>	<b>26.82 mg</b>
Equivalent: pyridoxine	17.11 mg
<b>riboflavin sodium phosphate</b>	<b>30 mg</b>
Equivalent: riboflavin	

Public Summary



**Australian Government**  
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<b>thiamine hydrochloride</b>	22.8 mg
Equivalent: thiamine	<b>113.36 mg</b>
	89.19 mg

**Other Ingredients (Excipients)**

**Acacia**

**calcium hydrogen phosphate dihydrate**

**colloidal anhydrous silica**

**edetic acid**

**Flavour**

**gellan gum**

**hypromellose**

**microcrystalline cellulose**

**Oryza sativa**

**potable water**

**potassium acetate**

**silicon dioxide**

**Sunflower Oil**

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Public Summary