



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:		337658	BioActivated B
ARTG entry for	Medicine Listed		
Sponsor	Biomedica Nutraceuticals Pty Ltd		
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia		
ARTG Start Date	10/06/2020		
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 . BioActivated B

Product Type	Single Medicine Product	Effective Date	26/03/2025
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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



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

Indication Requirements

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.

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

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.

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 serious immunological diseases.

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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range

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.

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

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

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

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thiamine hydrochloride	22.8 mg
Equivalent: thiamine	113.36 mg
	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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