



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	373898	BioActive B-Complex
ARTG entry for	Medicine Listed	
Sponsor	RN Labs Pty Ltd	
Postal Address	18 / 93 Rivergate Place, MURARRIE, QLD, 4172 Australia	
ARTG Start Date	31/08/2021	
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 . BioActive B-Complex

Product Type	Single Medicine Product	Effective Date	31/08/2021
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Permitted Indications

- Enhance/promote energy levels
- Helps enhance/promote general health and wellbeing
- Helps enhance/promote red blood cell health
- Maintain/support healthy cardiovascular system function
- Maintain/support healthy immune system function
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support (state vitamin/mineral) within normal range
- Support healthy stress response in the body
- Aid/assist/helps synthesis of neurotransmitters
- Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Product presentation must not imply or refer to serious immunological diseases.
- 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

WARNING - this medication may be dangerous when used in large amounts or for a long time; or WARNING - this product contains [insert pyridoxine hydrochloride or pyridoxal 5-phosphate as applicable], which may be dangerous when used in large amounts or for a long time.

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

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin 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

Biotin	500 microgram
calcium folinate	540 microgram
Equivalent: folic acid	500 microgram
calcium pantothenate	218 mg
Equivalent: pantothenic acid	200 mg
hydroxocobalamin	500 microgram
inositol	100 mg
nicotinamide	150 mg
pyridoxal 5-phosphate	29.2 mg
Equivalent: pyridoxine	20 mg
riboflavin sodium phosphate	25 mg
Equivalent: riboflavin	20 mg
thiamine hydrochloride	56 mg
Equivalent: thiamine	50 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

hypromellose

leucine

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