



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	361980 Hydroxy B Complex
ARTG entry for	Medicine Listed
Sponsor	Spectrumceuticals Pty Ltd
Postal Address	Unit 8/5 Narabang Way, BELROSE, NSW, 2085 Australia
ARTG Start Date	14/04/2021
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 . Hydroxy B Complex

Product Type	Single Medicine Product	Effective Date	19/08/2022
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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 levels
- Maintain/support eye health
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Maintain/support nail health/strength/thickness
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Helps decrease/reduce homocysteine levels in healthy individuals
- Aid/assist/helps protein synthesis in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Support healthy stress response in the body
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters

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Maintain/support nervous system health
 Maintain/support nervous system function
 Maintain/support skin health
 Maintain/support wound healing in healthy individuals
 Maintain/support skin repair/healing/regeneration in healthy individuals

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to chronic fatigue syndrome.
 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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
 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 vision correction, faults or serious eye disease e.g. macular degeneration.
 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

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

Biotin	400 microgram
calcium folinate	542 microgram
Equivalent: folic acid	500 microgram
calcium pantothenate	109.17 mg
Equivalent: pantothenic acid	100 mg
choline bitartrate	121.67 mg
Equivalent: choline	50 mg
hydroxocobalamin	500 microgram
nicotinamide	50 mg
pyridoxine hydrochloride	18.23 mg
Equivalent: pyridoxine	15 mg
riboflavin sodium phosphate	26.32 mg
Equivalent: riboflavin	20 mg
thiamine hydrochloride	95.32 mg
Equivalent: thiamine	75 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

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hypromellose

leucine

microcrystalline cellulose

potable water

silicon dioxide

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