



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	386340	Activated B6 P5P
ARTG entry for	Medicine Listed	
Sponsor	Spectrumceuticals Pty Ltd	
Postal Address	Unit 8/5 Narabang Way, BELROSE, NSW, 2085 Australia	
ARTG Start Date	28/03/2022	
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 . Activated B6 P5P

Product Type	Single Medicine Product	Effective Date	28/03/2022
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Permitted Indications

Maintain/support energy levels
Maintain/support general health and wellbeing
Aid/assist healthy red blood cell production
Helps maintain/support haemoglobin formation/synthesis
Maintain/support immune system health
Maintain/support healthy immune system function
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function

Indication Requirements

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 mental illnesses, disorders or conditions.
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).
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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



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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.

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.

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

pyridoxal 5-phosphate monohydrate	39.18 mg
Equivalent: pyridoxine	25 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

hypromellose

leucine

microcrystalline cellulose

potable water

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