Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	357138	Active B6
ARTG entry for	Medicine Listed	
Sponsor	RN Labs Pty Ltd	
Postal Address	18 / 93 Rivergate Place, MURARRIE, QLD, 4172 Australia	
ARTG Start Date	22/03/2021	
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 . Active B6

Product Type Single Medicine Product **Effective Date** 22/03/2021

Permitted Indications

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Maintain/support (state vitamin/mineral) within normal range

Aid/assist/helps synthesis of neurotransmitters

Decrease/reduce/relieve symptoms of premenstrual tension

Indication Requirements

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.

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

Public Summary

Visual Identification

Active Ingredients	
pyridoxal 5-phosphate	**50 mg**
Equivalent: pyridoxine	34.2 mg

Other Ingredients (Excipients)
colloidal anhydrous silica
hypromellose
leucine
microcrystalline cellulose