

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	448831	Sublingual Hydroxy-B12
ARTG entry for	Medicine Listed	
Sponsor	RN Labs Pty Ltd	1
Postal Address	18 / 93 Rivergate Australia	e Place, MURARRIE, QLD, 4172
ARTG Start Date	16/05/2024	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	S
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 . Sublingual Hydroxy-B12						
Product Type	Single Medicine Product	Effective Date	16/05/2024			
Permitted Indications						
Maintain/support general health and wellbeing						
Maintain/support red blood cell health						
Maintain/support healthy cardiovascular system function						
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency						
Maintain/support (state vitamin/mineral) within normal range						
Maintain/support nerve conduction						
Maintain/support nervous system health						
Indication Requirements						
Product presentation must not imply or refer to serious cardiovascular conditions.						
Product presentation must not imply or refer to mental illnesses, disorders or 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).						
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				
Components						
1. Formulation 1						

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This is not an ARTG Certificate document.

Produced at 04.06.2024 at 03:23:20 AEST

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Dosage FormTablet, uncoatedRoute of AdministrationOralVisual IdentificationActive IngredientshydroxocobalaminOther Ingredients (Excipients)ascorbyl palmitatecolloidal anhydrous silicahypromellosexylitol

1000 microgram

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