

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Products

Summary for ARTG Entry:	162502	Vitamin B3 500mg
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pt	y Ltd
Postal Address	PO Box 3143, KI Australia	RRAWEE, NSW, 2232
ARTG Start Date	16/06/2009	
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.

1 . Vitamin B3	1 . Vitamin B3 500mg					
Product Type	Single Medicine Product	Effective Date	20/12/2022			
Permitted Indications						
Aaintain/support energy production						
faintain/support general health and wellbeing						
Aid/assist/helps glucose/sugar/carbohydrate metabolism						
Maintain/support (state vitamin/mineral/nutrient) levels in the body						
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)						
Maintain/support skin health						
Indication Requirements						
If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.						
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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.						
Standard Indication	ons					
No Standard Indications included on Record						
Specific Indications						
No Specific Indications included on Record						
Warnings						
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						
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500 mg

Dosage Form Tablet, film coated Route of Administration Oral Visual Identification Active Ingredients nicotinamide **Other Ingredients (Excipients)** calcium hydrogen phosphate dihydrate colloidal anhydrous silica hypromellose macrogol 400 magnesium stearate microcrystalline cellulose sodium starch glycollate

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This is not an ARTG Certificate document.