



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	304901	Niacin 100mg Extended Release
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	Suite 802 Level 8 1-5 Chalmers Crescent Mascot, Sydney, NSW, 2020 Australia	
ARTG Start Date	21/06/2018	
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 . Niacin 100mg Extended Release

Product Type	Single Medicine Product	Effective Date	19/11/2025
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Permitted Indications

Helps convert (state food) into energy
Maintain/support energy production
Maintain/support general health and wellbeing
Aid/assist digestion/breakdown of dietary fat
Aid/assist/helps digestion of fats/fatty acids/triglycerides/lipid
Aid/assist digestion of glucose/sugar/carbohydrates
Aid/assist/helps glucose/sugar/carbohydrate metabolism
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.
Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.
Label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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	Tablet, modified release
Route of Administration	Oral
Visual Identification	
Active Ingredients	
nicotinic acid	100 mg
Other Ingredients (Excipients)	
calcium hydrogen phosphate dihydrate	
Carnauba Wax	
colloidal anhydrous silica	
croscarmellose sodium	
hypromellose	
macrogol 8000	
magnesium stearate	
microcrystalline cellulose	
povidone	
titanium dioxide	

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