



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	389803	Zinc Glycinate
ARTG entry for	Medicine Listed	
Sponsor	RN Labs Pty Ltd	
Postal Address	18 / 93 Rivergate Place, MURARRIE, QLD, 4172 Australia	
ARTG Start Date	8/06/2022	
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 . Zinc Glycinate

Product Type	Single Medicine Product	Effective Date	8/06/2022
---------------------	-------------------------	-----------------------	-----------

Permitted Indications

Maintain/support immune system health
Helps enhance/improve/promote immune system function
Maintain/support healthy immune system function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Maintain/support neuroendocrine function
Aid/assist/helps synthesis of neurotransmitters

Indication Requirements

Product presentation must not imply or refer to serious immunological diseases.
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 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

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
------------------	------------------------

Public Summary



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

zinc glycinate	125 mg
Equivalent: zinc	25 mg

Other Ingredients (Excipients)

citric acid

colloidal anhydrous silica

glycine

hypromellose

leucine

microcrystalline cellulose

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary