



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	373901	Tri-Factor (B6, Zn, Mg)
ARTG entry for	Medicine Listed	
Sponsor	RN Labs Pty Ltd	
Postal Address	18 / 93 Rivergate Place, MURARRIE, QLD, 4172 Australia	
ARTG Start Date	31/08/2021	
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 . Tri-Factor (B6, Zn, Mg)

Product Type	Single Medicine Product	Effective Date	31/08/2021
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Permitted Indications

Helps enhance/promote general health and wellbeing
Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body
Maintain/support nervous system function
Decrease/reduce/relieve symptoms of premenstrual tension
Linked indication - Helps reduce occurrence of premenstrual tension symptoms

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

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 mental illnesses, disorders or conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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
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Components

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1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

magnesium citrate	645 mg
Equivalent: magnesium	100 mg
pyridoxal 5-phosphate	21.9 mg
Equivalent: pyridoxine	15 mg
zinc citrate dihydrate	37.3 mg
Equivalent: zinc	12 mg

Other Ingredients (Excipients)

colloidal anhydrous silica

hypromellose

leucine

microcrystalline cellulose

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