



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	373901	Tri-Factor (B6, Zn, Mg)
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	RN Labs Pty Ltd	
<b>Postal Address</b>	18 / 93 Rivergate Place, MURARRIE, QLD, 4172 Australia	
<b>ARTG Start Date</b>	31/08/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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)

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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

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

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

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

<b>Pack Size</b>	<b>Poison Schedule</b>
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#### Components

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**1 . Formulation 1**

**Dosage Form** Capsule, hard  
**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

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

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
hypromellose  
leucine  
microcrystalline cellulose

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