



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

## Public Summary

|                                |   |         |
|--------------------------------|---|---------|
| <b>Summary for ARTG Entry:</b> | 394270  | L-5MTHF |
| <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<br>Australia |         |
| <b>ARTG Start Date</b>         | 23/08/2022  |         |
| <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 . L-5MTHF

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 23/08/2022 |
|---------------------|-------------------------|-----------------------|------------|

### Permitted Indications

Maintain/support general health and wellbeing  
Maintain/support red blood cell health  
Maintain/support healthy cardiovascular system function  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Maintain/support cognitive function/mental function  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system function

### Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.

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).

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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

No Warnings included on Record

### Additional Product information

### Pack Size/Poison information

|                  |                        |
|------------------|------------------------|
| <b>Pack Size</b> | <b>Poison Schedule</b> |
|------------------|------------------------|



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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

levomefolate glucosamine 902 microgram

Equivalent: levomefolic acid 500 microgram

Other Ingredients (Excipients)

colloidal anhydrous silica

hypromellose

leucine

microcrystalline cellulose

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