



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

## Public Summary

<b>Summary for ARTG Entry:</b>	383954	Medi Restore
<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>	14/02/2022	
<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 . Medi Restore

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	14/02/2022
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### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps enhance/promote general health and wellbeing
- Anti-inflammatory/relieve inflammation
- Maintain/support body tissue repair/regeneration
- Helps in the maintenance of a healthy body weight
- Maintain/support healthy digestive system function
- Maintain/support intestinal good/beneficial/friendly flora
- Maintain/support gastrointestinal mucosal membrane health
- Maintain/support healthy liver function
- Maintain/support healthy immune system function
- Maintain/support muscle health
- Maintain/support (state vitamin/mineral/nutrient) levels in the body

### Indication Requirements

- Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
- 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.
- 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 serious immunological diseases.
- Label statement: If symptoms persist, talk to your health professional.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings



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Contains caffeine [state quantity per dosage unit or per mL or per gram of product] total caffeine [per dosage unit or per mL or per gram]. A cup of instant coffee contains approximately 80mg of caffeine.

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).

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

Caffeine intake more than 200 mg per day is not recommended during pregnancy or breastfeeding.

**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

**1 . Formulation 1**

**Dosage Form** Powder

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>11.37 mg/g</b>
<b>Biotin</b>	<b>2.3 microgram/g</b>
<b>calcified lithothamnion species</b>	<b>7.09 mg/g</b>
Equivalent: calcium	2.27 mg/g
<b>calcium pantothenate</b>	<b>2.48 mg/g</b>
Equivalent: pantothenic acid	2.27 mg/g
<b>Camellia sinensis leaf Powder</b>	<b>11.36 mg/g</b>
<b>choline bitartrate</b>	<b>1.36 mg/g</b>
<b>chromium nicotinate</b>	<b>8.8 microgram/g</b>
Equivalent: chromium	1.1 microgram/g
<b>colecalfiferol</b>	<b>.45 microgram/g</b>
<b>glutamine</b>	<b>68.18 mg/g</b>
<b>glycine</b>	<b>68.18 mg/g</b>
<b>hydroxocobalamin</b>	<b>9.1 microgram/g</b>
<b>Larix arabinogalactan</b>	<b>45.46 mg/g</b>
<b>levomefolate glucosamine</b>	<b>16.4 microgram/g</b>
Equivalent: levomefolic acid	9.1 microgram/g
<b>magnesium citrate</b>	<b>14.99 mg/g</b>
Equivalent: magnesium	2.27 mg/g
<b>manganese gluconate</b>	<b>.3687 mg/g</b>
Equivalent: manganese	.0455 mg/g
<b>molybdenum trioxide</b>	<b>3.5 microgram/g</b>
Equivalent: molybdenum	2.3 microgram/g
<b>nicotinamide</b>	<b>2.27 mg/g</b>
<b>Oryza sativa seed Extract dry concentrate</b>	<b>454.5 mg/g</b>
Equivalent: Oryza sativa (Dry)	4.999 g/g
<b>Pisum sativum seed Extract dry concentrate</b>	<b>150.91 mg/g</b>
Equivalent: Pisum sativum (Dry)	754.55 mg/g
<b>potassium iodide</b>	<b>3 microgram/g</b>
Equivalent: iodine	2.3 microgram/g
<b>pyridoxal 5-phosphate monohydrate</b>	<b>.7132 mg/g</b>
Equivalent: pyridoxine	.455 mg/g
<b>riboflavin sodium phosphate</b>	<b>.2991 mg/g</b>
Equivalent: riboflavin	.2273 mg/g

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<b>selenomethionine</b>	<b>5.7 microgram/g</b>
Equivalent: selenium	2.3 microgram/g
<b>Silybum marianum fruit Extract dry concentrate standardised</b>	<b>6.82 mg/g</b>
Equivalent: Silybum marianum (Dry)	477.4 mg/g
<b>taurine</b>	<b>15.91 mg/g</b>
<b>thiamine hydrochloride</b>	<b>.9821 mg/g</b>
Equivalent: thiamine	.7727 mg/g
<b>zinc citrate dihydrate</b>	<b>2.12 mg/g</b>
Equivalent: zinc	.6818 mg/g
<b>Zingiber officinale rhizome Extract dry concentrate</b>	<b>6.14 mg/g</b>
Equivalent: Zingiber officinale (Dry)	61.4 mg/g

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
dl-alpha-tocopherol  
Flavour  
glycine  
medium chain triglycerides  
Siraitia grosvenorii  
Stevia rebaudiana  
vegetable oil  
xanthan gum

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