



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	287909	Medi Restore FRENCH VANILLA
ARTG entry for	Medicine Listed	
Sponsor	RN Labs Pty Ltd	
Postal Address	18 / 93 Rivergate Place, MURARRIE, QLD, 4172 Australia	
ARTG Start Date	13/04/2017	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 FRENCH VANILLA

Product Type	Effective Date
Single Medicine Product	13/06/2019

Permitted Indications

- Helps reduce/decrease free radical damage to body cells
- 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 protein stores
- 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.

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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

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.

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

ascorbic acid	10.93 mg/g
Biotin	2.18 microgram/g
calcified lithothamnion species	6.86 mg/g
Equivalent: calcium	2.18 mg/g
calcium pantothenate	2.4 mg/g
Equivalent: pantothenic acid	2.18 mg/g
Camellia sinensis leaf Powder	10.93 mg/g
choline dihydrogen citrate	1.31 mg/g
chromium nicotinate	8.74 microgram/g
Equivalent: chromium	1.09 microgram/g
colecalfiferol	.44 microgram/g
glutamine	65.56 mg/g
glycine	65.56 mg/g
hydroxocobalamin	8.74 microgram/g
Larix arabinogalactan	43.7 mg/g
levomefolate calcium	9.62 microgram/g
Equivalent: levomefolic acid	8.74 microgram/g
magnesium citrate	13.68 mg/g
Equivalent: magnesium	2.18 mg/g
manganese (II) glycinate	160 microgram/g
Equivalent: manganese	43.7 microgram/g
molybdenum trioxide	3.28 microgram/g
Equivalent: molybdenum	2.18 microgram/g
nicotinamide	2.18 mg/g
Oryza sativa seed Extract dry concentrate	437 mg/g
Equivalent: Oryza sativa (Dry)	4.37 g/g
palm tocotrienols complex	4.8 mg/g
Pisum sativum seed Extract dry concentrate	145 mg/g
Equivalent: Pisum sativum (Dry)	1.23 g/g
potassium iodide	2.84 microgram/g

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Equivalent: iodine	2.18 microgram/g
Punica granatum fruit peel Extract dry concentrate	8.74 mg/g
Equivalent: Punica granatum (Dry)	175 mg/g
pyridoxal 5-phosphate	.65 mg/g
Equivalent: pyridoxine	.45 mg/g
riboflavin sodium phosphate	.22 mg/g
Equivalent: riboflavin	.17 mg/g
selenomethionine	5.68 microgram/g
Equivalent: selenium	2.18 microgram/g
Silybum marianum seed Extract dry concentrate	6.55 mg/g
Equivalent: Silybum marianum (Dry)	458.5 mg/g
taurine	15.29 mg/g
thiamine hydrochloride	.87 mg/g
Equivalent: thiamine	.77 mg/g
zinc citrate	2 mg/g
Equivalent: zinc	.65 mg/g
Zingiber officinale rhizome Powder	5.9 mg/g
Other Ingredients (Excipients)	
colloidal anhydrous silica	
Flavour	
hypromellose	
medium chain triglycerides	
Siraitia grosvenorii	
Steviol glycosides	
xanthan gum	
xylitol	

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