Public Summary

Summary for ARTG Entry:	270094 TraceMins Complex
ARTG entry for	Medicine Listed
Sponsor	RN Labs Pty Ltd
Postal Address	18 / 93 Rivergate Place, MURARRIE, QLD, 4172 Australia
ARTG Start Date	15/02/2016
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 . TraceMins Complex

Product Type	Single Medicine Product	**Effective Date**	29/08/2019

Permitted Indications

Helps reduce/decrease free radical damage to body cells
Maintain/support healthy growth and development
Helps enhance/promote general health and wellbeing
Maintain/support hair health
Maintain/support bone health
Helps maintain/support healthy blood sugar/glucose
Maintain/support healthy thyroid hormones
Enhance/improve/promote immune defence/immunity
Maintain/support healthy immune system function
Aid/assist/helps glucose/sugar/carbohydrate metabolism
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support reproductive system health
Maintain/support healthy reproductive hormones
Maintain/support testosterone level
Helps enhance/promote skin health
Maintain/support skin repair/healing/regeneration

Indication Requirements

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Product presentation must not imply or refer to any thyroid related diseases.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to hormone imbalances.

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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.

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).

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

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

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

chromium nicotinate	**200 microgram**
Equivalent: chromium	25 microgram
colloidal anhydrous silica	**8 mg**
manganese (II) glycinate	**7.4 mg**
Equivalent: manganese	2 mg
molybdenum trioxide	**90 microgram**
Equivalent: molybdenum	60 microgram
selenomethionine	**130 microgram**
Equivalent: selenium	50 microgram
zinc citrate dihydrate	**62.2 mg**
Equivalent: zinc	20 mg

Other Ingredients (Excipients)

leucine

microcrystalline cellulose

tapioca starch

Public Summary