



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	308009	Ultimate Multi & Antioxidant
ARTG entry for	Medicine Listed	
Sponsor	NRC Nutrition Pty Ltd	
Postal Address	PO Box 1248, Coolum Beach, QLD, 4573 Australia	
ARTG Start Date	9/08/2018	
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.

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 . Ultimate Multi & Antioxidant

Product Type	Single Medicine Product	Effective Date	23/06/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support energy levels
- Helps enhance/promote general health and wellbeing
- Maintain/support general health and wellbeing
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Helps maintain/support healthy blood sugar/glucose
- Maintain/support healthy thyroid gland function
- Maintain/support immune system health
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support skin health

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 chronic fatigue syndrome.
- Product presentation must not imply or refer to any thyroid related diseases.
- Label statement: 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.
- Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.
- Product presentation must not imply or refer to serious immunological diseases.

Standard Indications

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

This product 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

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard
Route of Administration Oral

Visual Identification

Active Ingredients

alpha lipoic acid	150 mg
Biotin	100 microgram
calcium folinate	135 microgram
Equivalent: folic acid	125 microgram
calcium pantothenate	27.29 mg
Equivalent: pantothenic acid	25 mg
choline bitartrate	25 mg
chromium picolinate	101 microgram
Equivalent: chromium	12.5 microgram
colecalfiferol	.0062 mg
colloidal anhydrous silica	6 mg
Dunaliella salina	10 mg
hydroxocobalamin	250 microgram
inositol	25 mg
magnesium amino acid chelate	125 mg
Equivalent: magnesium	25 mg
magnesium ascorbate monohydrate	55.72 mg
Equivalent: ascorbic acid	50 mg
Equivalent: magnesium	3.45 mg
manganese amino acid chelate	5 mg
Equivalent: manganese	500 microgram
mixed (low-alpha type) tocopherols concentrate	50.001 mg
nicotinamide	10 mg
potassium iodide	65.4 microgram
Equivalent: iodine	50 microgram
pyridoxal 5-phosphate monohydrate	19.59 mg
Equivalent: pyridoxine	12.5 mg
riboflavin sodium phosphate	13.16 mg

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Equivalent: riboflavin	10 mg
selenomethionine	93.1 microgram
Equivalent: selenium	37.5 microgram
thiamine hydrochloride	12.71 mg
Equivalent: thiamine	10 mg
zinc citrate dihydrate	38.9 mg
Equivalent: zinc	12.5 mg

Other Ingredients (Excipients)

Acacia
ascorbyl palmitate
colloidal anhydrous silica
dl-alpha-tocopherol
edetic acid
Gelatin
gellan gum
hypromellose
maize starch
medium chain triglycerides
microcrystalline cellulose
mixed (low-alpha type) tocopherols concentrate
potable water
potassium acetate
silicon dioxide
Soya Oil
starch sodium octenyl succinate
sucrose

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