



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	308010	Preconception Multi for Men
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	NRC Nutrition Pty Ltd	
<b>Postal Address</b>	PO Box 1248, Coolum Beach, QLD, 4573 Australia	
<b>ARTG Start Date</b>	9/08/2018	
<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.

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 . Preconception Multi for Men**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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
- 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
- Helps enhance/promote preconception health
- Maintain/support reproductive system health
- Maintain/support healthy reproductive hormones
- Helps maintain/support testosterone formation/synthesis
- Maintain/support sperm health
- Maintain/support sperm motility
- Maintain/support sperm production
- Maintain/support testosterone level
- Maintain/support skin health

**Indication Requirements**

Product presentation must not imply or refer to chronic fatigue syndrome.  
 If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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Product presentation must not imply or refer to infertility.

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.

Product presentation must not imply or refer to hormone imbalances.

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

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

**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 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**

<b>alpha lipoic acid</b>	<b>150 mg</b>
<b>Biotin</b>	<b>100 microgram</b>
<b>calcium folinate</b>	<b>135 microgram</b>
Equivalent: folic acid	125 microgram
<b>calcium pantothenate</b>	<b>27.29 mg</b>
Equivalent: pantothenic acid	25 mg
<b>choline bitartrate</b>	<b>25 mg</b>
<b>chromium picolinate</b>	<b>101 microgram</b>
Equivalent: chromium	12.5 microgram
<b>colecalfiferol</b>	<b>.0062 mg</b>
<b>colloidal anhydrous silica</b>	<b>6 mg</b>
<b>Dunaliella salina</b>	<b>10 mg</b>
<b>hydroxocobalamin</b>	<b>250 microgram</b>
<b>inositol</b>	<b>25 mg</b>
<b>magnesium amino acid chelate</b>	<b>125 mg</b>
Equivalent: magnesium	25 mg
<b>magnesium ascorbate monohydrate</b>	<b>55.72 mg</b>
Equivalent: ascorbic acid	50 mg

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Equivalent: magnesium	3.45 mg
<b>manganese amino acid chelate</b>	<b>5 mg</b>
Equivalent: manganese	500 microgram
<b>mixed (low-alpha type) tocopherols concentrate</b>	<b>50.001 mg</b>
<b>nicotinamide</b>	<b>10 mg</b>
<b>potassium iodide</b>	<b>65.4 microgram</b>
Equivalent: iodine	50 microgram
<b>pyridoxal 5-phosphate monohydrate</b>	<b>19.59 mg</b>
Equivalent: pyridoxine	12.5 mg
<b>riboflavin sodium phosphate</b>	<b>13.16 mg</b>
Equivalent: riboflavin	10 mg
<b>selenomethionine</b>	<b>93.1 microgram</b>
Equivalent: selenium	37.5 microgram
<b>thiamine hydrochloride</b>	<b>12.71 mg</b>
Equivalent: thiamine	10 mg
<b>zinc citrate dihydrate</b>	<b>38.9 mg</b>
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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