



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	354664	Preconception Multi for Women
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	NRC Nutrition Pty Ltd	
<b>Postal Address</b>	PO Box 1248, Coolumb Beach, QLD, 4573 Australia	
<b>ARTG Start Date</b>	9/02/2021	
<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 . Preconception Multi for Women**

Product Type	Single Medicine Product	Effective Date	21/02/2021
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support energy levels
- 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 red blood cell health
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support healthy thyroid gland function
- Maintain/support healthy thyroid hormones
- Maintain/support healthy thyroid hormones
- Maintain/support thyroid gland health
- Maintain/support immune system health
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Helps decrease/reduce homocysteine levels
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support female reproductive system health
- Helps maintains/support healthy foetal CNS/brain development
- Maintains/support healthy foetal development
- Maintain/support healthy pregnancy
- Maintain/support preconception health
- Helps prepare the body for pregnancy
- Maintain/support healthy reproductive hormones
- Maintain/support skin health

**Indication Requirements**

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

Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Product presentation must not imply or refer to infertility.

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 hormone imbalances.

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 cardiovascular conditions.

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

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to chronic fatigue syndrome.

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

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Do not take while on warfarin therapy without medical advice.

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.

Not for the treatment of iron deficiency conditions (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.

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	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>betacarotene</b>	<b>1 mg</b>
<b>Biotin</b>	<b>200 microgram</b>
<b>calcium folinate</b>	<b>108 microgram</b>
Equivalent: folic acid	100 microgram
<b>calcium pantothenate</b>	<b>27.29 mg</b>
Equivalent: pantothenic acid	25 mg
<b>choline bitartrate</b>	<b>100 mg</b>
<b>chromium picolinate</b>	<b>201.1 microgram</b>
Equivalent: chromium	25 microgram
<b>colecalfiferol</b>	<b>.0125 mg</b>
<b>colloidal anhydrous silica</b>	<b>10 mg</b>
<b>hydroxocobalamin</b>	<b>250 microgram</b>
<b>inositol</b>	<b>25 mg</b>



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<b>iron (II) glycinate</b>	<b>43.83 mg</b>
Equivalent: iron	12 mg
<b>levomefolate glucosamine</b>	<b>267 microgram</b>
Equivalent: levomefolic acid	150 microgram
<b>magnesium ascorbate monohydrate</b>	<b>47.65 mg</b>
Equivalent: magnesium	2.95 mg
Equivalent: ascorbic acid	42.5 mg
<b>magnesium citrate</b>	<b>304.85 mg</b>
Equivalent: magnesium	47.1 mg
<b>manganese amino acid chelate</b>	<b>10 mg</b>
Equivalent: manganese	1 mg
<b>molybdenum trioxide</b>	<b>37.5 microgram</b>
Equivalent: molybdenum	25 microgram
<b>nicotinamide</b>	<b>20 mg</b>
<b>potassium iodide</b>	<b>176.6 microgram</b>
Equivalent: iodine	135 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>62.1 microgram</b>
Equivalent: selenium	25 microgram
<b>Tagetes erecta flower Extract dry concentrate</b>	<b>2 mg</b>
Equivalent: Tagetes erecta (Fresh)	1100 mg
<b>thiamine hydrochloride</b>	<b>12.71 mg</b>
Equivalent: thiamine	10 mg
<b>ubidecarenone</b>	<b>30 mg</b>
<b>zinc citrate dihydrate</b>	<b>37.38 mg</b>
Equivalent: zinc	12 mg

**Other Ingredients (Excipients)**

Acacia  
ascorbyl palmitate  
d-alpha-tocopherol  
edetic acid  
fractionated coconut oil  
gellan gum  
hypromellose  
liquid glucose  
microcrystalline cellulose  
mixed (low-alpha type) tocopherols concentrate  
Pea Starch  
potable water  
potassium acetate  
purified water  
silicon dioxide  
sodium alginate  
sodium ascorbate  
sucrose  
tapioca starch

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