



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

## Public Summary

|                                |  |                               |
|--------------------------------|--|-------------------------------|
| <b>Summary for ARTG Entry:</b> | 373899   | 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<br>Australia |                               |
| <b>ARTG Start Date</b>         | 31/08/2021   |                               |
| <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

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 31/08/2021 |
|---------------------|-------------------------|-----------------------|------------|

### 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 serious cardiovascular conditions.

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

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 chronic fatigue syndrome.

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 any thyroid related diseases.

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

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

Product presentation must not imply or refer to infertility.

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

If directed to women, 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 hormone imbalances.

**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.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin 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.

Not for the treatment of iron deficiency conditions (or words to that effect).

**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>110 microgram</b>   |
| Equivalent: folic acid            | 100 microgram          |
| <b>calcium pantothenate</b>       | <b>27.18 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>44.4 mg</b>         |
| Equivalent: iron                                     | 12 mg                  |
| <b>levomefolate glucosamine</b>                      | <b>294 microgram</b>   |
| Equivalent: levomefolic acid                         | 150 microgram          |
| <b>magnesium ascorbate monohydrate</b>               | <b>47.36 mg</b>        |
| Equivalent: ascorbic acid                            | 42.5 mg                |
| Equivalent: magnesium                                | 2.93 mg                |
| <b>magnesium citrate</b>                             | <b>291.41 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>13.67 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>20 mg</b>           |
| Equivalent: Tagetes erecta (Dry)                     | 960 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>37.33 mg</b>        |
| Equivalent: zinc                                     | 12 mg                  |

**Other Ingredients (Excipients)**

Acacia  
ascorbyl palmitate  
citric acid  
d-alpha-tocopherol  
dl-alpha-tocopherol  
edetic acid  
fractionated coconut oil  
gellan gum  
hypromellose  
liquid glucose  
maltodextrin  
microcrystalline cellulose  
modified food starch  
Pea Starch  
potable water  
potassium acetate  
purified water  
silicon dioxide  
sodium alginate  
sodium ascorbate

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