



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	411659	Preconception Multi for Men
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	NRC Nutrition Pty Ltd	
<b>Postal Address</b>	PO Box 380, Peregrine Beach, QLD, 4573 Australia	
<b>ARTG Start Date</b>	29/06/2023	
<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 Men

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	29/06/2023
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Helps reduce/decrease free radical damage to body cells  
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 healthy thyroid gland function  
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  
Helps enhance/promote preconception health  
Maintain/support preconception health  
Maintain/support reproductive system health  
Maintain/support healthy reproductive hormones  
Helps maintain/support testosterone formation/synthesis  
Maintain/support semen health  
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 any thyroid related diseases.  
Product presentation must not imply or refer to mental illnesses, disorders or conditions.



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Product presentation must not imply or refer to infertility.

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

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 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.

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 immunological diseases.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

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

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

Do not take while on warfarin therapy without medical advice.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

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.

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).

#### 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
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#### Components

##### 1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

##### Visual Identification

#### Active Ingredients

Biotin	100 microgram
calcium folinate	271 microgram
Equivalent: folic acid	250 microgram
calcium pantothenate	54.59 mg
Equivalent: pantothenic acid	50 mg
choline bitartrate	243.13 mg
Equivalent: choline	100 mg
chromium picolinate	201 microgram
Equivalent: chromium	25 microgram
colecalfiferol	.0125 mg
colloidal anhydrous silica	5 mg
hydroxocobalamin	500 microgram
Lycopersicon esculentum fruit Extract dry concentrate standardised	15 mg



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Equivalent: Lycopersicon esculentum (Dry)	1.5 g
<b>magnesium amino acid chelate</b>	<b>125 mg</b>
Equivalent: magnesium	25 mg
<b>magnesium ascorbate monohydrate</b>	<b>112.08 mg</b>
Equivalent: ascorbic acid	100 mg
Equivalent: magnesium	6.94 mg
<b>nicotinamide</b>	<b>10 mg</b>
<b>palm tocotrienols complex</b>	<b>5.001 mg</b>
<b>potassium iodide</b>	<b>130.8 microgram</b>
Equivalent: potassium	30.8 microgram
Equivalent: iodine	100 microgram
<b>pyridoxal 5-phosphate monohydrate</b>	<b>7.84 mg</b>
Equivalent: pyridoxine	5 mg
<b>retinol acetate</b>	<b>.414 mg</b>
Equivalent: vitamin A	.351 mg
<b>riboflavin sodium phosphate</b>	<b>6.58 mg</b>
Equivalent: riboflavin	5 mg
<b>selenomethionine</b>	<b>186 microgram</b>
Equivalent: selenium	75 microgram
<b>thiamine hydrochloride</b>	<b>19.06 mg</b>
Equivalent: thiamine	15 mg
<b>ubidecarenone</b>	<b>50 mg</b>
<b>zinc citrate dihydrate</b>	<b>77.77 mg</b>
Equivalent: zinc	25 mg

**Other Ingredients (Excipients)**

Acacia  
calcium hydrogen phosphate dihydrate  
carrageenan  
colloidal anhydrous silica  
d-alpha-tocopherol  
dl-alpha-tocopherol  
fractionated coconut oil  
gellan gum  
liquid glucose  
maize starch  
maltodextrin  
medium chain triglycerides  
Palm Fruit Oil  
potassium chloride  
pullulan  
purified water  
silicon dioxide  
sodium ascorbate  
spray-dried glucose syrup  
starch sodium octenyl succinate  
xanthan gum

Public Summary