



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	354454	Preconception Multi for Men
ARTG entry for	Medicine Listed	
Sponsor	NRC Nutrition Pty Ltd	
Postal Address	PO Box 1248, Coolum Beach, QLD, 4573 Australia	
ARTG Start Date	8/02/2021	
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.

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

Product Type	Single Medicine Product	Effective Date	28/05/2021
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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 infertility.
- Product presentation must not imply or refer to chronic fatigue syndrome.



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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 mental illnesses, disorders or conditions.

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 hormone imbalances.

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

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

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

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

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.

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).

Do not take while on warfarin therapy without medical advice.

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

Biotin	100 microgram
calcium folinate	271.27 microgram
Equivalent: folic acid	250 microgram
calcium pantothenate	54.56 mg
Equivalent: pantothenic acid	50 mg
choline bitartrate	100 mg
Equivalent: choline	41.13 mg
chromium picolinate	201.13 microgram
Equivalent: chromium	25 microgram
colecalfiferol	.0125 mg
colloidal anhydrous silica	12 mg
hydroxocobalamin	500 microgram
Lycopersicon esculentum fruit Extract dry concentrate standardised	15 mg

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Equivalent: Lycopersicon esculentum (Dry)	1.5 g
magnesium ascorbate monohydrate	112.08 mg
Equivalent: magnesium	6.94 mg
Equivalent: ascorbic acid	100 mg
magnesium citrate	154.32 mg
Equivalent: magnesium	25 mg
nicotinamide	20 mg
palm tocotrienols complex	5.001 mg
potassium iodide	130.8 microgram
Equivalent: iodine	100 microgram
Equivalent: potassium	30.8 microgram
pyridoxal 5-phosphate monohydrate	23.51 mg
Equivalent: pyridoxine	15 mg
retinol acetate	.414 mg
Equivalent: vitamin A	.351 mg
riboflavin sodium phosphate	19.74 mg
Equivalent: riboflavin	15 mg
selenomethionine	186.29 microgram
Equivalent: selenium	75 microgram
thiamine hydrochloride	19.06 mg
Equivalent: thiamine	15 mg
ubidecarenone	50 mg
zinc citrate dihydrate	77.88 mg
Equivalent: zinc	25 mg

Other Ingredients (Excipients)

Acacia
ascorbyl palmitate
colloidal anhydrous silica
d-alpha-tocopherol
dl-alpha-tocopherol
edetic acid
fractionated coconut oil
gellan gum
hypromellose
liquid glucose
maize starch
maltodextrin
microcrystalline cellulose
Palm Fruit Oil
potable water
potassium acetate
silicon dioxide
sodium ascorbate
starch sodium octenyl succinate

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