



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	373899	Preconception Multi for Women
ARTG entry for	Medicine Listed	
Sponsor	NRC Nutrition Pty Ltd	
Postal Address	PO Box 380, Peregrin Beach, QLD, 4573 Australia	
ARTG Start Date	31/08/2021	
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 Women

Product Type	Single Medicine Product	Effective Date	31/08/2021
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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.

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.

Product presentation must not imply or refer to infertility.

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

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 serious cardiovascular conditions.

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

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 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

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.

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.

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

betacarotene	1 mg
Biotin	200 microgram
calcium folinate	110 microgram
Equivalent: folic acid	100 microgram
calcium pantothenate	27.18 mg
Equivalent: pantothenic acid	25 mg
choline bitartrate	100 mg
chromium picolinate	201.1 microgram
Equivalent: chromium	25 microgram
colecalfiferol	.0125 mg
colloidal anhydrous silica	10 mg
hydroxocobalamin	250 microgram
inositol	25 mg

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iron (II) glycinate	44.4 mg
Equivalent: iron	12 mg
levomefolate glucosamine	294 microgram
Equivalent: levomefolic acid	150 microgram
magnesium ascorbate monohydrate	47.36 mg
Equivalent: ascorbic acid	42.5 mg
Equivalent: magnesium	2.93 mg
magnesium citrate	291.41 mg
Equivalent: magnesium	47.1 mg
manganese amino acid chelate	10 mg
Equivalent: manganese	1 mg
molybdenum trioxide	37.5 microgram
Equivalent: molybdenum	25 microgram
nicotinamide	20 mg
potassium iodide	176.6 microgram
Equivalent: iodine	135 microgram
pyridoxal 5-phosphate monohydrate	19.59 mg
Equivalent: pyridoxine	12.5 mg
riboflavin sodium phosphate	13.67 mg
Equivalent: riboflavin	10 mg
selenomethionine	62.1 microgram
Equivalent: selenium	25 microgram
Tagetes erecta flower Extract dry concentrate	20 mg
Equivalent: Tagetes erecta (Dry)	960 mg
thiamine hydrochloride	12.71 mg
Equivalent: thiamine	10 mg
ubidecarenone	30 mg
zinc citrate dihydrate	37.33 mg
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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