



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	411861	Preconception Multi for Women
ARTG entry for	Medicine Listed	
Sponsor	NRC Nutrition Pty Ltd	
Postal Address	PO Box 380, Peregrine Beach, QLD, 4573 Australia	
ARTG Start Date	30/06/2023	
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	30/06/2023
---------------------	-------------------------	-----------------------	------------

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



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

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 serious immunological diseases.

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.

Product presentation must not imply or refer to hormone imbalances.

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

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.

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

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).

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.

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

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.

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

betacarotene	1 mg
Biotin	200 microgram
calcium pantothenate	27.29 mg
Equivalent: pantothenic acid	25 mg
choline bitartrate	291.76 mg
Equivalent: choline	120 mg
chromium picolinate	201.1 microgram
Equivalent: chromium	25 microgram
colecalfiferol	.0125 mg
colloidal anhydrous silica	7 mg
hydroxocobalamin	250 microgram
inositol	25 mg
iron (II) glycinate	44.4 mg

Public Summary



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Equivalent: iron	12 mg
levomefolate glucosamine	451 microgram
Equivalent: levomefolic acid	250 microgram
magnesium amino acid chelate	125 mg
Equivalent: magnesium	25 mg
magnesium ascorbate monohydrate	47.36 mg
Equivalent: ascorbic acid	42.5 mg
Equivalent: magnesium	2.93 mg
manganese amino acid chelate	10 mg
Equivalent: manganese	1 mg
molybdenum trioxide	37.5 microgram
Equivalent: molybdenum	25 microgram
nicotinamide	10 mg
potassium iodide	177 microgram
Equivalent: iodine	135 microgram
pyridoxal 5-phosphate monohydrate	7.84 mg
Equivalent: pyridoxine	5 mg
riboflavin sodium phosphate	6.58 mg
Equivalent: riboflavin	5 mg
selenomethionine	80.7 microgram
Equivalent: selenium	32.5 microgram
Tagetes erecta flower Extract dry concentrate	20 mg
Equivalent: Tagetes erecta (Dry)	960 mg
thiamine hydrochloride	19.06 mg
Equivalent: thiamine	15 mg
ubidecarenone	50 mg
zinc citrate dihydrate	37.38 mg
Equivalent: zinc	12 mg

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
carrageenan
d-alpha-tocopherol
fractionated coconut oil
gellan gum
liquid glucose
medium chain triglycerides
Pea Starch
potassium chloride
pullulan
purified water
silicon dioxide
sodium alginate
sodium ascorbate
xanthan gum

Public Summary