



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	374060 Prenatal Trimester 2 & 3 Plus Breastfeeding
ARTG entry for	Medicine Listed
Sponsor	NRC Nutrition Pty Ltd
Postal Address	PO Box 380, Peregian Beach, QLD, 4573 Australia
ARTG Start Date	2/09/2021
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 . Prenatal Trimester 2 & 3 Plus Breastfeeding

Product Type	Single Medicine Product	Effective Date	2/09/2021
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Permitted Indications

- Helps maintains/support healthy foetal CNS/brain development
- Maintains/support healthy foetal development
- Maintain/support healthy pregnancy
- Maintain/support maternal health
- Maintain/support placenta health/growth
- Helps enhance/promote maternal postnatal health

Indication Requirements

- Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.
- 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.

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.
- 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).
- 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
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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
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

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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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