



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	330544	Prenatal Trimester One with Ginger
ARTG entry for	Medicine Listed	
Sponsor	NRC Nutrition Pty Ltd	
Postal Address	PO Box 1248, Coolumb Beach, QLD, 4573 Australia	
ARTG Start Date	28/02/2020	
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 One with Ginger

Product Type	Single Medicine Product	Effective Date	22/08/2021
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Permitted Indications

Helps maintains/support healthy foetal CNS/brain development

Enhance/promote healthy foetal development

Maintain/support healthy pregnancy

Decrease/reduce/relieve morning sickness

Maintain/support placenta health/growth

Indication Requirements

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

Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral 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 - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
[Contains vitamin B6].

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



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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Biotin	200 microgram
calcium pantothenate	27.29 mg
Equivalent: pantothenic acid	25 mg
choline bitartrate	25 mg
chromium picolinate	201.1 microgram
Equivalent: chromium	25 microgram
colecalfiferol	.0062 mg
colloidal anhydrous silica	5 mg
hydroxocobalamin	250 microgram
inositol	25 mg
levomefolate glucosamine	445 microgram
Equivalent: levomefolic acid	250 microgram
magnesium ascorbate monohydrate	56.04 mg
Equivalent: magnesium	3.47 mg
Equivalent: ascorbic acid	50 mg
magnesium citrate	308.64 mg
Equivalent: magnesium	50 mg
manganese amino acid chelate	20 mg
Equivalent: manganese	2 mg
molybdenum trioxide	37.5 microgram
Equivalent: molybdenum	25 microgram
nicotinamide	15 mg
potassium iodide	98.1 microgram
Equivalent: iodine	75 microgram
pyridoxal 5-phosphate monohydrate	19.59 mg
Equivalent: pyridoxine	12.5 mg
pyridoxine hydrochloride	30.39 mg
Equivalent: pyridoxine	25 mg
riboflavin sodium phosphate	3.29 mg
Equivalent: riboflavin	2.5 mg
selenomethionine	62.1 microgram
Equivalent: selenium	25 microgram
thiamine hydrochloride	3.18 mg
Equivalent: thiamine	2.5 mg
zinc citrate dihydrate	17.13 mg
Equivalent: zinc	5.5 mg
Zingiber officinale rhizome Extract dry concentrate	65 mg
Equivalent: Zingiber officinale (Dry)	650 mg

Other Ingredients (Excipients)

Acacia

ascorbyl palmitate

colloidal anhydrous silica

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d-alpha-tocopherol
disodium edetate
fractionated coconut oil
gellan gum
hypromellose
liquid glucose
microcrystalline cellulose
potable water
potassium acetate
silicon dioxide
sodium ascorbate

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