



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	355905	Prenatal Pro
ARTG entry for	Medicine Listed	
Sponsor	Designs For Health Pty Ltd	
Postal Address	1 / 418 Pittwater Road, North Manly, NSW, 2100 Australia	
ARTG Start Date	1/03/2021	
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 Pro

Product Type	Single Medicine Product	Effective Date	1/03/2021
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Permitted Indications

- Aid/assist healthy red blood cell production
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in breast fed healthy infants
- Helps maintains/support healthy foetal CNS/brain development
- Maintains/support healthy foetal development
- Maintain/support healthy pregnancy
- Maintain/support maternal health
- Maintain/support preconception health

Indication Requirements

- 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 serious cardiovascular conditions.
- If product is indicated for supplementation, 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).
- Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.
- Product presentation must not imply or refer to infertility.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.



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Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard
Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	66.67 mg
betacarotene	2 mg
Biotin	100 microgram
Bixa orellana seed Extract dry concentrate	5.47 mg
Equivalent: Bixa orellana (Dry)	1.8215 g
calcium amino acid chelate	83.35 mg
Equivalent: calcium	16.7 mg
calcium pantothenate	10.92 mg
Equivalent: pantothenic acid	10 mg
Equivalent: calcium	916 microgram
choline bitartrate	111.52 mg
Equivalent: choline	45.87 mg
chromium nicotinate	83.33 microgram
Equivalent: chromium	10 microgram
colecalfiferol	.0083 mg
copper gluconate	2.39 mg
Equivalent: copper	335 microgram
inositol	13.33 mg
iron (II) glycinate	15.82 mg
Equivalent: iron	4.33 mg
levomefolate glucosamine	300.45 microgram
Equivalent: levomefolic acid	166.6 microgram
magnesium glycinate	189.14 mg
Equivalent: magnesium	26.67 mg
manganese amino acid chelate	6.67 mg
Equivalent: manganese	667 microgram
mecobalamin (co-methylcobalamin)	167 microgram
menaquinone 7	.0066 mg
molybdenum trioxide	25.01 microgram
Equivalent: molybdenum	16.7 microgram
nicotinamide	11.67 mg
phytomenadione	40 microgram
potassium iodide	95.49 microgram
Equivalent: iodine	73 microgram
Equivalent: potassium	23 microgram
pyridoxal 5-phosphate monohydrate	10.45 mg
Equivalent: pyridoxine	6.67 mg
riboflavin sodium phosphate	13.7 mg
Equivalent: riboflavin	10 mg
selenomethionine	66.27 microgram

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Equivalent: selenium	27 microgram
thiamine hydrochloride	11.21 mg
Equivalent: thiamine	10 mg
zinc glycinate	23.65 mg
Equivalent: zinc	6.67 mg

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
calcium phosphate
citric acid
colloidal anhydrous silica
d-alpha-tocopherol
fractionated coconut oil
hypromellose
liquid glucose
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
modified food starch
Pea Starch
purified water
silicon dioxide
sodium alginate
sodium ascorbate
sucrose

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