



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	290544	Pregnancy Plus 1-2-3
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	22/06/2017	
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 . Pregnancy Plus 1-2-3

Product Type	Single Medicine Product	Effective Date	3/09/2021
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Permitted Indications

Maintain/support general health and wellbeing in breastfeeding women
Helps maintains/support healthy foetal CNS/brain development
Maintains/support healthy foetal development
Maintain/support healthy pregnancy
Maintain/support maternal health in breastfeeding women
Maintain/support maternal health
Help to prevent neural tube defects such as spina bifida and/or anencephaly
Maintain/support preconception health
Aid/assist healthy thyroid hormone production for pregnancy
Maintain/support healthy thyroid gland function for pregnancy

Indication Requirements

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.
Label statement: If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine.
Product presentation must not imply or refer to any thyroid related diseases.
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 infertility.
Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
Indication can only be used for medicines that contain iodine as a mandatory component of one or more permitted active ingredients and the recommended daily dose of the medicine provides a minimum of 150 micrograms of iodine.
Indication can only be used for medicines that contain folic acid as an active ingredient and the recommended daily dose of the medicine provides a minimum of 400 micrograms of folic acid. Product presentation referring to the prevention of neural tube defects must include at least one of the following label statements: when trying to conceive and during the first trimester of pregnancy, and/or when taken at least four weeks before conception and during the first trimester of pregnancy.

Standard Indications

No Standard Indications included on Record

Specific Indications



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No Specific Indications included on Record

Warnings

Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida, seek specific medical advice (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.

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

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

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	50 mg
betacarotene	3 mg
Biotin	200 microgram
calcium folinate	69.44 microgram
Equivalent: folic acid	50 microgram
calcium pantothenate	20 mg
Equivalent: calcium	1.68 mg
Equivalent: pantothenic acid	18.32 mg
calcium phosphate	68.5 mg
Equivalent: calcium	25 mg
Equivalent: phosphorus	12.3 mg
choline bitartrate	75 mg
Equivalent: choline	31.16 mg
chromium picolinate	201 microgram
Equivalent: chromium	25 microgram
colecalfiferol	.0125 mg
folic acid	200 microgram
inositol	10 mg
iron amino acid chelate	50 mg
Equivalent: iron	5 mg
magnesium amino acid chelate	100 mg
Equivalent: magnesium	20 mg
manganese amino acid chelate	10 mg
Equivalent: manganese	1 mg
mecobalamin (co-methylcobalamin)	250 microgram
mixed (low-alpha type) tocopherols concentrate	5.001 mg
molybdenum trioxide	38 microgram
Equivalent: molybdenum	25 microgram
nicotinamide	20 mg
potassium iodide	176 microgram
Equivalent: iodine	135 microgram

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pyridoxine hydrochloride	50 mg
Equivalent: pyridoxine	41.13 mg
riboflavin	20 mg
selenomethionine	62 microgram
Equivalent: selenium	25 microgram
thiamine nitrate	20 mg
zinc citrate dihydrate	31.15 mg
Equivalent: zinc	10 mg

Other Ingredients (Excipients)

Acacia
Carnauba Wax
chlorophyllin-copper complex
colloidal anhydrous silica
croscarmellose sodium
crospovidone
dl-alpha-tocopherol
hypromellose
macrogol 8000
magnesium stearate
maize starch
medium chain triglycerides
microcrystalline cellulose
potable water
povidone
purified water
silicon dioxide
Soya Oil
starch sodium octenyl succinate
sucrose
titanium dioxide
vanillin

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