



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	357176	Pregnancy Multi
ARTG entry for	Medicine Listed	
Sponsor	Factors Group Australia Pty Ltd	
Postal Address	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
ARTG Start Date	22/03/2021	
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 . Pregnancy Multi

Product Type	Single Medicine Product	Effective Date	22/03/2021
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Permitted Indications

- Maintain/support general health and wellbeing
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support (state vitamin/mineral) within normal range
- Helps maintains/support healthy foetal CNS/brain development
- Maintains/support healthy foetal development
- Maintain/support healthy pregnancy
- Maintain/support maternal health
- Help to prevent neural tube defects such as spina bifida and/or anencephaly
- Helps prepare the body for pregnancy

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: [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.
- 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.
- 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.

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Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin 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.

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Allium sativum bulb Powder	2.5 mg
Equivalent: Allium sativum (Fresh)	25 mg
Arthrospira platensis	2.5 mg
Ascophyllum nodosum whole plant Powder standardised	18.75 mg
betacarotene	2 mg
borax	1.535 mg
Equivalent: boron	.175 mg
Brassica oleracea var. viridis leaf Powder	2.5 mg
calcified lithothamnion species	154.5491 mg
Equivalent: calcium	48.805 mg
Equivalent: magnesium	3.579 mg
calcium ascorbate dihydrate	11.08 mg
Equivalent: calcium	1.195 mg
Equivalent: ascorbic acid	10 mg
calcium pantothenate	2.7293 mg
Equivalent: pantothenic acid	2.5 mg
Camellia sinensis leaf Extract dry concentrate	2.5 mg
Equivalent: Camellia sinensis (Dry)	75 mg
Chlorella vulgaris whole plant Powder	2.5 mg
choline bitartrate	15.1957 mg
Equivalent: choline	6.25 mg
chromium picolinate	201.126 microgram
Equivalent: chromium	25 microgram
Citrus sinensis fruit Extract dry concentrate	2.5 mg
Equivalent: Citrus sinensis (Dry)	875 mg
colecalfiferol	.0125 mg
cupric sulfate	982.3 microgram
Equivalent: copper	250 microgram
Cynara scolymus leaf Powder	2.5 mg
d-alpha-tocopheryl acid succinate	5 mg
Echinacea purpurea whole plant Powder	2.5 mg
Euterpe oleracea fruit Juice powder	2.5 mg
ferric pyrophosphate	40.026 mg
Equivalent: iron	12 mg
Fragaria vesca fruit Powder	.25 mg
Hordeum vulgare leaf Juice powder	2.5 mg
inositol	12.5 mg

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levomefolate glucosamine	345.54 microgram
Equivalent: levomefolic acid	200 microgram
lutein	.25 mg
lycopene	.25 mg
Lycopersicon esculentum fruit Powder	2.5 mg
magnesium ascorbate	10.83 mg
Equivalent: magnesium	1.083 mg
Equivalent: ascorbic acid	7.738 mg
magnesium aspartate	151.69 mg
Equivalent: magnesium	30.338 mg
magnesium citrate	92.5926 mg
Equivalent: magnesium	15 mg
manganese gluconate	5.4825 mg
Equivalent: manganese	.625 mg
mecobalamin	100 microgram
menaquinone 7	20 microgram
nicotinamide	6.25 mg
Phyllanthus emblica fruit Extract dry concentrate standardised	9.524 mg
Equivalent: Phyllanthus emblica (Dry)	476.2 mg
Punica granatum fruit Powder	.25 mg
Punica granatum fruit hull Extract dry concentrate	2.5 mg
Equivalent: Punica granatum (Dry)	50 mg
pyridoxal 5-phosphate monohydrate	1.0146 mg
Equivalent: pyridoxine	.625 mg
riboflavin sodium phosphate	.8546 mg
Equivalent: riboflavin	.625 mg
Rubus idaeus fruit Powder	.25 mg
Schisandra chinensis fruit Extract dry concentrate	2.5 mg
Equivalent: Schisandra chinensis (Dry)	50 mg
selenomethionine	62.0902 microgram
Equivalent: selenium	25 microgram
thiamine hydrochloride	1.5887 mg
Equivalent: thiamine	1.25 mg
Vaccinium macrocarpon fruit Powder	.25 mg
Vaccinium macrocarpon fruit Powder	5 mg
Vaccinium myrtillus fruit Powder	.25 mg
Vitis vinifera seed Extract dry concentrate	2 mg
Equivalent: Vitis vinifera (Dry)	200 mg
Vitis vinifera seed Extract dry concentrate	21.5 mg
Equivalent: Vitis vinifera (Dry)	795.5 mg
zinc citrate dihydrate	15.65 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

Acacia
ascorbic acid
ascorbyl palmitate
calcium hydrogen phosphate
colloidal anhydrous silica
croscarmellose sodium
d-alpha-tocopherol

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dl-alpha-tocopherol
dl-alpha-tocopheryl acetate
fractionated coconut oil
glucose
glycerol
hydrolysed maize starch
hypolose
hypromellose
lecithin
magnesium stearate
maize starch
maltodextrin
maltose
microcrystalline cellulose
mixed (high-alpha type) tocopherols concentrate
mono- and di- glycerides
potable water
pregelatinised maize starch
silicon dioxide
sodium ascorbate
sodium chloride
starch sodium octenyl succinate
stearic acid
sucrose
Sunflower Oil

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