Public Summary

Summary for ARTG Entry:	351517	METAGENICS PREGNANCY CARE ADVANCED

ARTG entry for	Medicine Listed
Sponsor	Metagenics (Aust) Pty Ltd
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia
ARTG Start Date	10/12/2020
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 . METAGENICS PREGNANCY CARE ADVANCED

Product Type	Single Medicine Product	**Effective Date**	5/08/2022

Permitted Indications

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in breast fed healthy infants

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in breastfeeding women

Maintains/support healthy foetal development

Maintain/support healthy pregnancy

Help to prevent neural tube defects such as spina bifida and/or anencephaly

Maintain/support preconception health

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).

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.

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

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

If symptoms persist consult your healthcare practitioner (or words to that effect).

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.

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).

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Child resistant closure	Not recorded

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

betacarotene	**3 mg**
Biotin	**35 microgram**
calcium ascorbate dihydrate	**60.52 mg**
Equivalent: ascorbic acid	50 mg
calcium pantothenate	**12.5 mg**
choline bitartrate	**167.76 mg**
Equivalent: choline	69 mg
chromium nicotinate	**250 microgram**
Equivalent: chromium	25 microgram
colecalciferol	**.0125 mg**
folic acid	**200 microgram**
iron amino acid chelate	**60 mg**
Equivalent: iron	12 mg
levomefolate glucosamine	**89.24 microgram**
Equivalent: levomefolic acid	49.97 microgram
lutein	**1 mg**
manganese amino acid chelate	**7.81 mg**
Equivalent: manganese	1.25 mg
mecobalamin (co-methylcobalamin)	**249.82 microgram**
menaquinone 7	**.015 mg**
molybdenum trioxide	**37.51 microgram**
Equivalent: molybdenum	25 microgram
nicotinamide	**15 mg**
potassium iodide	**195.56 microgram**
Equivalent: iodine	149.51 microgram
pyridoxal 5-phosphate monohydrate	**12.5 mg**
Equivalent: pyridoxine	7.98 mg
pyridoxine hydrochloride	**12.52 mg**
Equivalent: pyridoxine	10.3 mg
riboflavin sodium phosphate	**12.5 mg**
selenomethionine	**62.5 microgram**
Equivalent: selenium	25 microgram
thiamine hydrochloride	**12.5 mg**
zinc amino acid chelate	**50 mg**
Equivalent: zinc	10 mg

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
calcium hydrogen phosphate
calcium phosphate
citric acid
Colour
croscarmellose sodium
crospovidone
d-alpha-tocopherol
dl-alpha-tocopherol
fractionated coconut oil
hypromellose
liquid glucose
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
silicon dioxide
sodium ascorbate
starch sodium octenyl succinate
sucrose
tartaric acid