



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	351517	METAGENICS PREGNANCY CARE ADVANCED
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	10/12/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/08/2022
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#### Permitted Indications

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

Product presentation must not imply or refer to infertility.  
If directed to women, 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 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: [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).

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



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[Contains vitamin B6].

**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**

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

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

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**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

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