



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

## Public Summary

<b>Summary for ARTG Entry:</b>	345445	Prenatal Methyl
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	MTHFR Support Australia Pty Ltd	
<b>Postal Address</b>	PO Box 1265, Neutral Bay Junction, NSW, 2089 Australia	
<b>ARTG Start Date</b>	6/10/2020	
<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 . Prenatal Methyl

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	22/10/2020
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Maintain/support collagen formation  
Maintain/support energy levels  
Maintain/support energy production  
Maintain/support body mucous membrane health  
Maintain/support general health and wellbeing  
Maintain/support connective tissue health  
Aid/assist/helps connective tissue production/formation  
Maintain/support healthy body tissues  
Maintain/support bone health  
Aids/assists healthy bone development/growth/building  
Maintain/support bone strength  
Help maintain/support bone mineralisation  
Aid/assist healthy red blood cell production  
Maintain/support red blood cell health  
Maintain/support blood health  
Helps maintain/support haemoglobin formation/synthesis  
Maintain/support heart health  
Maintain/support blood capillary health  
Maintain/support blood vessel health  
Maintain/support healthy thyroid gland function  
Maintain/support healthy thyroid hormones  
Maintain/support thyroid gland health  
Aid/assist thyroid hormone production  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support muscle function

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Maintain/support muscle function  
Maintain/support healthy neuromuscular system/function  
Aid/assist/helps glucose/sugar/carbohydrate metabolism  
Aid/assist/helps protein synthesis in the body  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)  
Maintain/support (state vitamin/mineral/nutrient) levels in the body when sun exposure is inadequate  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Aids/assists the body to cope with environmental stress  
Support healthy stress response in the body  
Maintain/support cognitive function/mental function  
Maintain/support nerve conduction  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system health  
Maintain/support nervous system function  
Maintain/support female reproductive system health  
Maintains/support healthy foetal development  
Maintain/support healthy pregnancy  
Maintain/support maternal health  
Maintain/support preconception health in healthy males  
Maintain/support preconception health in healthy females  
Maintain/support placenta health/growth  
Maintain/support reproductive system health in males  
Maintain/support healthy reproductive hormones  
Maintain/support sperm health in healthy males  
Maintain/support sperm motility in healthy males  
Maintain/support sperm production in healthy males  
Maintain/support testosterone level  
Maintain/support skin health  
Maintain/support skin integrity/structure  
Maintain/support skin regeneration  
Maintain/support wound healing

#### Indication Requirements

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.  
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to any thyroid related diseases.

Product presentation must not imply or refer to serious immunological diseases.

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).

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).

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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 hormone imbalances.

Product presentation must not imply or refer to chronic fatigue syndrome.

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 serious musculoskeletal or neurological conditions.



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Label statement: If symptoms persist, talk to your health professional.

#### 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.

Do not take while on warfarin therapy without medical advice.

#### Additional Product information

#### Pack Size/Poison information

##### Pack Size

##### Poison Schedule

#### Components

##### 1 . Formulation 1

**Dosage Form** Capsule, hard

**Route of Administration** Oral

##### Visual Identification

#### Active Ingredients

alpha lipoic acid	10 mg
ascorbic acid	66.66 mg
betacarotene	.5 mg
Biotin	100 microgram
calcium citrate tetrahydrate	158.1 mg
Equivalent: calcium	33.33 mg
calcium pantothenate	43.49 mg
Equivalent: calcium	3.65 mg
Equivalent: pantothenic acid	39.84 mg
choline bitartrate	66.66 mg
Equivalent: choline	27.42 mg
chromium picolinate	119 microgram
Equivalent: chromium	14.8 microgram
colecalfiferol	.0083 mg
d-alpha-tocopheryl acid succinate	55.09 mg
hydroxocobalamin	83.4 microgram
inositol	8.33 mg
levomefolate calcium	180.45 microgram
Equivalent: levomefolic acid	166.6 microgram
magnesium citrate	102.9 mg
Equivalent: magnesium	16.67 mg
manganese (II) glycinate	6.16 mg
Equivalent: manganese	1.67 mg
mecobalamin (co-methylcobalamin)	83.4 microgram
nicotinamide	10 mg
phytomenadione	20 microgram
potassium iodide	87.1 microgram
Equivalent: iodine	66.6 microgram
pyridoxal 5-phosphate monohydrate	7.99 mg
Equivalent: pyridoxine	5.1 mg

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<b>riboflavin sodium phosphate</b>	<b>11.392 mg</b>
Equivalent: riboflavin	8.34 mg
<b>selenomethionine</b>	<b>124 microgram</b>
Equivalent: selenium	50 microgram
<b>sodium molybdate dihydrate</b>	<b>65.8 microgram</b>
Equivalent: molybdenum	26.1 microgram
<b>thiamine hydrochloride</b>	<b>14.7197 mg</b>
<b>ubidecarenone</b>	<b>16.66 mg</b>
<b>zinc citrate dihydrate</b>	<b>25.96 mg</b>
Equivalent: zinc	8.33 mg

**Other Ingredients (Excipients)**

Acacia  
ascorbyl palmitate  
citric acid  
colloidal anhydrous silica  
d-alpha-tocopherol  
disodium edetate  
gellan gum  
hypromellose  
leucine  
maize starch  
maltodextrin  
medium chain triglycerides  
Pea Starch  
potable water  
potassium acetate  
purified water  
silicon dioxide  
sodium alginate  
sodium ascorbate  
sucrose

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