



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

## Public Summary

<b>Summary for ARTG Entry:</b>	271955	Metagenics Metagen Methyl-Active
<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>	2/03/2016	
<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 Metagen Methyl-Active

Product Type	Single Medicine Product	Effective Date	18/12/2020
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### Permitted Indications

- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Maintain/support cardiovascular system health
- Helps decrease/reduce homocysteine levels
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Decrease/reduce/relieve symptoms of stress
- Maintain/support cognitive function/mental function
- Aid/assist/helps synthesis of neurotransmitters
- Support healthy emotional/mood balance

### Indication Requirements

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 mental illnesses, disorders or conditions.  
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).  
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



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

**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**

<b>levomefolate calcium</b>	<b>540.54 microgram</b>
Equivalent: levomefolic acid	500 microgram
<b>mecobalamin (co-methylcobalamin)</b>	<b>1000 microgram</b>
<b>pyridoxal 5-phosphate monohydrate</b>	<b>40 mg</b>
Equivalent: pyridoxine	25.52 mg
<b>riboflavin sodium phosphate</b>	<b>27.4 mg</b>
Equivalent: riboflavin	20 mg
<b>serine</b>	<b>100 mg</b>

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
disodium edetate  
gellan gum  
hypromellose  
magnesium stearate  
microcrystalline cellulose  
potable water  
potassium acetate

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