



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	232441	Methyl-Max
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Limited	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	8/01/2015	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Methyl-Max

Product Type	Effective Date
Single Medicine Product	6/05/2020

### Permitted Indications

Maintain/support energy levels  
Aid/assist healthy red blood cell production  
Helps maintain/support haemoglobin formation/synthesis  
Helps decrease/reduce homocysteine levels  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system function  
Maintains/support healthy foetal development

### Indication Requirements

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: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.  
Product presentation must not imply or refer to chronic fatigue syndrome.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.



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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**

**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>calcium folinate</b>	<b>694 microgram</b>
Equivalent: folic acid	500 microgram
<b>cyanocobalamin</b>	<b>500 microgram</b>
<b>pyridoxal 5-phosphate monohydrate</b>	<b>31.34 mg</b>
Equivalent: pyridoxine	20 mg
<b>riboflavin</b>	<b>15 mg</b>
<b>serine</b>	<b>50 mg</b>

**Other Ingredients (Excipients)**

calcium phosphate  
colloidal anhydrous silica  
hypromellose  
magnesium stearate  
microcrystalline cellulose  
purified water

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