



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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

Product Type	Single Medicine Product	Effective Date	8/03/2024
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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 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.

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

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].

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).

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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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		
calcium folinate		694 microgram
Equivalent: folic acid		500 microgram
cyanocobalamin		500 microgram
pyridoxal 5-phosphate monohydrate		31.34 mg
Equivalent: pyridoxine		20 mg
riboflavin		15 mg
serine		50 mg
Other Ingredients (Excipients)		
calcium phosphate		
colloidal anhydrous silica		
hypromellose		
magnesium stearate		
microcrystalline cellulose		
purified water		

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