



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	276085	Methyl BioActive
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	1/06/2016	
Product Category	Medicine	
Status	Active	
Approval Area	Listed Medicines	

Conditions

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 BioActive

Product Type	Single Medicine Product	Effective Date	14/04/2020
---------------------	-------------------------	-----------------------	------------

Permitted Indications

- Maintain/support energy levels
- Maintain/support energy production
- Aid/assist healthy red blood cell production
- Helps maintain/support haemoglobin formation/synthesis
- Helps decrease/reduce homocysteine levels
- 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.
- 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.
- 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
------------------	------------------------

Components

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

choline bitartrate	300 mg
levomefolate calcium	542 microgram
Equivalent: levomefolic acid	500 microgram
mecobalamin (co-methylcobalamin)	1 mg
pyridoxal 5-phosphate monohydrate	51.09 mg
Equivalent: pyridoxine	32.6 mg
riboflavin sodium phosphate	32.89 mg
Equivalent: riboflavin	25 mg
serine	50 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
crospovidone
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
potable water
povidone
purified water
silicon dioxide

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary