Australian Government

Department of Health and Aged Care

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 serious cardiovascular conditions.

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.

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

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

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

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