



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	398610	Total B Methyl
ARTG entry for	Medicine Listed	
Sponsor	MTHFR Support Australia Pty Ltd	
Postal Address	PO Box 1265, Neutral Bay Junction, NSW, 2089 Australia	
ARTG Start Date	31/10/2022	
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 . Total B Methyl

Product Type	Single Medicine Product	Effective Date	31/10/2022
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body when dietary intake is inadequate
Maintain/support energy levels when dietary intake is inadequate
Helps convert (state food) into energy when dietary intake is inadequate
Maintain/support energy production when dietary intake is inadequate
Maintain/support healthy eye function when dietary intake is inadequate
Maintain/support eye health when dietary intake is inadequate
Maintain/support body mucous membrane health when dietary intake is inadequate
Maintain/support general health and wellbeing when dietary intake is inadequate
Maintain/support hair growth when dietary intake is inadequate
Maintain/support hair health when dietary intake is inadequate
Aid/assist nail growth when dietary intake is inadequate
Maintain/support nail health/strength/thickness when dietary intake is inadequate
Aid/assist/helps connective tissue production/formation when dietary intake is inadequate
Maintain/support healthy body tissues when dietary intake is inadequate
Aid/assist healthy red blood cell production when dietary intake is inadequate
Maintain/support red blood cell health when dietary intake is inadequate
Maintain/support blood health when dietary intake is inadequate
Helps maintain/support haemoglobin formation/synthesis when dietary intake is inadequate
Helps maintain/support healthy heart function when dietary intake is inadequate
Maintain/support heart health when dietary intake is inadequate
Maintain/support immune system health when dietary intake is inadequate
Maintain/support healthy immune system function when dietary intake is inadequate
Maintain/support muscle function when dietary intake is inadequate
Aid/assist/helps protein synthesis in the body when dietary intake is inadequate
Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient) when dietary intake is inadequate
Maintain/support (state vitamin/mineral) within normal range when dietary intake is inadequate



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Aids/assists the body to cope with environmental stress when dietary intake is inadequate
Support healthy stress response in the body when dietary intake is inadequate
Maintain/support general mental wellbeing when dietary intake is inadequate
Maintain/support nerve conduction when dietary intake is inadequate
Aid/assist/helps synthesis of neurotransmitters when dietary intake is inadequate
Maintain/support nervous system health when dietary intake is inadequate
Maintain/support nervous system function when dietary intake is inadequate
Maintain/support skin health when dietary intake is inadequate

Indication Requirements

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to serious cardiovascular conditions.

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

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 vision correction, faults or serious eye disease e.g. macular degeneration.

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 serious immunological diseases.

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].

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

Biotin	500 microgram
calcium pantothenate	196.51 mg
Equivalent: pantothenic acid	180 mg
levomefolate calcium	433.6 microgram
Equivalent: levomefolic acid	400 microgram
mecobalamin (co-methylcobalamin)	400 microgram
nicotinamide	130 mg
pyridoxal 5-phosphate monohydrate	23.51 mg
Equivalent: pyridoxine	15 mg
riboflavin sodium phosphate	32.89 mg
Equivalent: riboflavin	25 mg
thiamine hydrochloride	63.55 mg
Equivalent: thiamine	50 mg

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Other Ingredients (Excipients)

ascorbyl palmitate
colloidal anhydrous silica
hypromellose
leucine
potable water

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