



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	352660	Starter B
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	7/01/2021	
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 . Starter B

Product Type	Single Medicine Product	Effective Date	7/01/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support energy levels
- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Aid/assist nail growth
- Maintain/support nail health/strength/thickness
- Aid/assist/helps connective tissue production/formation
- Maintain/support healthy body tissues
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support heart health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle function
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Aids/assists the body to cope with environmental stress
- Support healthy stress response in the body
- Maintain/support nerve conduction

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Aid/assist/helps synthesis of neurotransmitters
 Maintain/support nervous system health
 Maintain/support nervous system function
 Maintain/support skin health

Indication Requirements

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

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
nicotinamide	130 mg
pyridoxal 5-phosphate monohydrate	23.51 mg
Equivalent: pyridoxine	15 mg
riboflavin sodium phosphate	25 mg
Equivalent: riboflavin	19.67 mg
thiamine hydrochloride	63.55 mg
Equivalent: thiamine	50 mg

Other Ingredients (Excipients)

ascorbyl palmitate

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

leucine

potable water

potassium acetate

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