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

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

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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