



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	365753	Met5Folate Choline
ARTG entry for	Medicine Listed	
Sponsor	Spectrumceuticals Pty Ltd	
Postal Address	10/5 Narabang Way, BELROSE, NSW, 2085 Australia	
ARTG Start Date	13/05/2021	
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 . Met5Folate Choline

Product Type	Single Medicine Product	Effective Date	1/06/2021
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Permitted Indications

Maintain/support healthy growth and development
Maintain/support general health and wellbeing
Aid/assist healthy red blood cell production
Maintain/support red blood cell health
Maintain/support blood health
Maintain/support cardiovascular system health
Maintain/support healthy cardiovascular system function
Maintain/support healthy liver function
Maintain/support liver health
Helps decrease/reduce homocysteine levels in healthy individuals
Aid/assist/helps protein synthesis in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support cognitive development
Maintain/support cognitive function/mental function
Maintain/support learning and information processing
Maintain/support memory/mental recall
Maintain/support brain function
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support healthy pregnancy

Indication Requirements

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



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

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 liver disease, such as cirrhosis, hepatitis.

Product presentation must not imply or refer to neurological conditions or developmental delays.

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

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

choline bitartrate	607.83 mg
Equivalent: choline	250 mg
levomefolate glucosamine	300.58 microgram
Equivalent: levomefolic acid	166.66 microgram
mecobalamin (co-methylcobalamin)	333.33 microgram

Other Ingredients (Excipients)

colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
leucine
microcrystalline cellulose
potable water
potassium acetate
silicon dioxide

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