



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	365753	Met5Folate Choline
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Spectrumceuticals Pty Ltd	
<b>Postal Address</b>	10/5 Narabang Way, BELROSE, NSW, 2085 Australia	
<b>ARTG Start Date</b>	13/05/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	1/06/2021
---------------------	-------------------------	-----------------------	-----------

### 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 mental illnesses, disorders or conditions.
- 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

Public Summary



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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

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: [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).

**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
-----------	-----------------

**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Capsule, hard
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

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

**Other Ingredients (Excipients)**

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

Public Summary

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.