



## Australian Government

### Department of Health and Aged Care

#### Therapeutic Goods Administration

<b>Record Summary</b>	445966	5-MTHF Biologically Active Folate
<b>Sponsor</b>	Vitopharm Biotech Pty Ltd	
<b>Therapeutic Type</b>	Medicine	
<b>Product Category</b>	Listed	
<b>ARTG Start Date</b>	19/04/2024	
<b>Postal Address</b>	SE 603/100 Walker St, North Sydney, NSW, 2060 Australia	
<b>Billing Address</b>	SE 603/100 Walker St, North Sydney, NSW, 2060 Australia	
<b>Product Type</b>	Medicine - - Listed	
<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.

#### Manufacturers

Name	Address	Manufacturing steps
Australian Laboratory Services Pty Ltd	Unit 10 2-8 South Street RYDALMERE , NSW , 2116 Australia	Testing chemical and physical
Chem-Chrom Laboratories and Services	Unit 15 / 10-12 Montore Road Minto , NSW , 2566 Australia	Testing chemical and physical
Ferngrove Pharmaceuticals Australia Pty Ltd	5 Ferngrove Place SOUTH GRANVILLE , NSW , 2142 Australia	Packaging and labelling Testing chemical and physical Secondary packaging Release for supply Manufacture of dosage form
Naturalab Pty Ltd	Level 2 / 111 Stephens Road BOTANY , NSW , 2019 Australia	Testing chemical and physical
Silliker Australia Pty Ltd	Unit C2 / 391 Park Road Regents Park Estate REGENTS PARK , NSW , 2143 Australia	Testing microbial
Southern Cross Analytical Research Laboratory	Level 3 T Block and N Block Military Road Southern Cross University LISMORE , NSW , 2480 Australia	Testing chemical and physical
Symbio Laboratories PTY LTD	2 Sirius Road Lane Cove West , NSW , 2066 Australia	Testing microbial

#### Products

1 . 5-MTHF Biologically Active Folate
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Record Summary

Permitted Indications

Maintain/support general health and wellbeing when dietary intake is inadequate  
Aid/assist healthy red blood cell production when dietary intake is inadequate  
Maintain/support blood health 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  
Maintain/support healthy pregnancy  
Maintain/support maternal health  
Maintain/support placenta health/growth

Indication Requirements

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).  
Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.  
  
Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.  
If directed to women, 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 serious cardiovascular 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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Specific Conditions

No Specific Conditions included on Record

Components

1 . Formulation 1

Dosage Form                      Tablet, film coated  
Route of Administration        Oral  
Maximum Daily Dose            1

Formulations

Active Ingredients	Category	Quantity	Units
levomefolate calcium	AAN	460	microgram
Equivalent			
levomefolic acid		400	microgram

Excipient Ingredients	Category	Quantity	Units
Carnauba Wax	AHS		
colloidal anhydrous silica	AAN		
croscarmellose sodium	AAN		
hypromellose	AAN		
macrogol 400	AAN		
magnesium stearate	AAN		
microcrystalline cellulose	AAN		
povidone	AAN		
titanium dioxide	AAN		