



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Vitopharm Biotech Pty Ltd

for approval to supply

5-MTHF Biologically Active Folate

ARTG Identifier AUST L 445966

ARTG Start Date 19/04/2024

Product Type Listed Medicine

Manufacturer Details	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 , 20 19 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 , 24 80 Australia	Testing chemical and physical
Symbio Laboratories PTY LTD	2 Sirius Road Lane Cove West , NSW , 2066 Australia	Testing microbial

ARTG Standard Conditions

The above Medicine Listed has been entered on the Register subject to the following 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 Covered by This Entry

1. 5-MTHF Biologically Active Folate

Product Specific Conditions

No specific conditions have been recorded against this entry.

Product 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

Product 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).

Product Standard Indications

No standard indications have been recorded against this entry.

Product Specific Indications

No specific indications have been recorded against this entry.

Warnings

No warnings have been recorded against this entry.

Dosage Form

- Tablet, film coated

Route of Administration

- Oral

Visual Identification

Additional Product information

Product Formulation(s)

Active Ingredients

	Quantity	Units
levomefolate calcium	460	microgram

