



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	233205	Folinic Acid
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Pty Ltd	
Postal Address	Blackmores Limited, PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	29/01/2015	
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 . Folinic Acid

Product Type	Single Medicine Product	Effective Date	17/09/2025
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Helps convert (state food) into energy
Relieve weariness/tiredness/fatigue/feeling of weakness
Aid/assist healthy red blood cell production
Maintain/support healthy immune system function
Helps decrease/reduce homocysteine levels
Aid/assist/helps synthesis of neurotransmitters
Helps maintains/support healthy foetal CNS/brain development
Maintains/support healthy foetal development

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.
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 immunological diseases.

Label statement: If symptoms persist, talk to your health professional.
Product presentation must not imply or refer to chronic fatigue syndrome.
Product presentation must not imply or refer to serious cardiovascular conditions.

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



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Pack Size/Poison information		
Pack Size		Poison Schedule
Components		
1 . Formulation 1		
Dosage Form	Capsule, hard	
Route of Administration	Oral	
Visual Identification		
Active Ingredients		
calcium folinate		.6944 mg
Equivalent: folic acid		.5 mg
Other Ingredients (Excipients)		
calcium hydrogen phosphate dihydrate		
colloidal anhydrous silica		
croscarmellose sodium		
hypromellose		
liquid paraffin		
magnesium stearate		
microcrystalline cellulose		
purified water		

© 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>.