



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	185582	Acetyl-L-Carnitine
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	17/06/2011	
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 . Acetyl-L-Carnitine

Product Type	Single Medicine Product	Effective Date	2/07/2021
---------------------	-------------------------	-----------------------	-----------

Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support energy levels in individuals over 65 years
Maintain/support energy levels
Maintain/support energy production
Maintain/support physical endurance/capacity/stamina
Maintain/support physical endurance/capacity/stamina in individuals over 65 years
Maintain/support general health and wellbeing in aging individuals
Maintain/support healthy body fat/muscle composition in aging individuals
Helps maintain/support healthy cholesterol
Maintain/support heart health
Aid/assist/helps post exercise recovery
Helps enhance/improve muscle recovery time in healthy males
Decrease/reduce mental/cognitive fatigue in individuals over 65 years
Enhance/improve/promote/increase cognitive performance in individuals over 65 years
Maintain/support cognitive function/mental function in individuals over 65 years
Maintain/support memory/mental recall in elderly individuals
Maintain/support brain function
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system function
Maintain/support reproductive system health in males
Maintain/support healthy sexual function in males
Maintain/support sperm health
Maintain/support sperm motility
Maintain/support sperm production

Indication Requirements

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



Australian Government
Department of Health
Therapeutic Goods Administration

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

Product presentation must not imply or refer to chronic fatigue syndrome.

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.

Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range

Product presentation must not imply or refer to infertility.

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

Pack Size/Poison information

Pack Size	Poison Schedule
-----------	-----------------

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

acetyl levocarnitine hydrochloride 500 mg

Other Ingredients (Excipients)

Gelatin

magnesium stearate

microcrystalline cellulose

purified water

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>.