



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	2/07/2021
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### 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 in individuals over 65 years  
Maintain/support physical endurance/capacity/stamina  
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 chronic fatigue syndrome.

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

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

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 infertility.

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

**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

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