



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	311848	Orthoplex Acetyl-L-Carnitine
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	23/11/2018	
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 . Orthoplex Acetyl-L-Carnitine

Product Type	Single Medicine Product	Effective Date	20/10/2025
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Permitted Indications

Maintain/support energy levels
Maintain/support general health and wellbeing
Maintain/support brain function
Maintain/support brain health
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Support healthy emotional/mood balance in healthy individuals
Maintain/support reproductive system health in healthy 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.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
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

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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)	
colloidal anhydrous silica	
disodium edetate	
gellan gum	
glycine	
hypromellose	
microcrystalline cellulose	
potable water	
potassium acetate	

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