



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	281113	Orthoplex MitoLift
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	7/10/2016	
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 MitoLift

Product Type	Single Medicine Product	Effective Date	19/12/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support natural liver cleansing/detoxification processes
- Maintain/support energy production
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support hair growth
- Maintain/support hair health
- Maintain/support nail health/strength/thickness
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support smell sensation
- Maintain/support taste sensation
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Helps decrease/reduce homocysteine levels in healthy individuals
- Aid/assist/helps protein synthesis in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in aging individuals

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Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy individuals
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support preconception health
Maintain/support skin health
Maintain/support skin repair/healing/regeneration in healthy individuals
Antioxidant/Reduce free radicals formed in the body
Helps reduce/decrease free radical damage to body cells
Maintain/support natural liver cleansing/detoxification processes
Maintain/support energy production
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Maintain/support muscle function
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Helps decrease/reduce homocysteine levels in healthy individuals
Aid/assist/helps protein synthesis in the body
Maintain/support (state vitamin/mineral/nutrient) levels in the body in aging individuals
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy individuals
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
Maintain/support nerve conduction
Aid/assist/helps synthesis of neurotransmitters
Maintain/support nervous system health
Maintain/support nervous system function
Maintain/support preconception health
Maintain/support skin health
Maintain/support skin repair/healing/regeneration in healthy individuals

Indication Requirements

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.
Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
Product presentation must not imply or refer to serious immunological diseases.
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 presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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Label statement: If symptoms persist, talk to your health professional.

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 only refer to detoxification in relation to natural body processes.

Product presentation must not imply or refer to drugs/alcohol.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist, seek the advice of a healthcare professional.

Do not take while on warfarin therapy without medical advice.

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Seek professional advice before long term use.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

acetyl levocarnitine hydrochloride	50 mg
alpha lipoic acid	50 mg
Biotin	1.5 microgram
calcium folinate	432.15 microgram
Equivalent: folic acid	400 microgram
creatine monohydrate	100 mg
cyanocobalamin	400 microgram
cysteine	50 mg
d-alpha-tocopheryl acid succinate	10 mg
magnesium orotate dihydrate	100 mg
Equivalent: magnesium	6.56 mg
nicotinamide	50 mg
phytomenadione	.05 mg
pyridoxal 5-phosphate	7.3 mg
Equivalent: pyridoxine	5 mg
riboflavin sodium phosphate	20 mg
Equivalent: riboflavin	14.6 mg
thiamine hydrochloride	15 mg
ubidecarenone	50 mg
zinc citrate dihydrate	15.63 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate

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Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
povidone
sucrose

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Pack Size **Poison Schedule**

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Visual Identification

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- Carnauba Wax
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- hypromellose
- macrogol 400
- magnesium stearate
- microcrystalline cellulose
- povidone
- sucrose

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