



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

**Public Summary**

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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 in aging individuals
- Maintain/support (state vitamin/mineral/nutrient) levels in the body

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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  
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 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**

Product presentation must not imply or refer to drugs/alcohol.  
Product presentation must only refer to detoxification in relation to natural body processes.  
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 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.  
Label statement: If symptoms persist, talk to your health professional.  
Product presentation must not imply or refer to serious cardiovascular conditions.

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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 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 infertility.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose 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**

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

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.

Do not take while on warfarin therapy without medical advice.

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**

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

**2 . Orthoplex MitoLift**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	4/11/2021
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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
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- 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
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- Maintain/support nervous system function
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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  
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**Indication Requirements**

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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**



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Do not take while on warfarin therapy without medical advice.

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

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Equivalent: zinc	5 mg

**Other Ingredients (Excipients)**

- Acacia**
- calcium hydrogen phosphate dihydrate**
- Carnauba Wax**
- colloidal anhydrous silica**
- croscarmellose sodium**
- crospovidone**
- hypromellose**
- macrogol 400**
- magnesium stearate**
- microcrystalline cellulose**
- povidone**
- sucrose**

Public Summary

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