



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

## Public Summary

<b>Summary for ARTG Entry:</b>	317425	Orthoplex Ultra Buffered C Powder
<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>	10/05/2019	
<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 Ultra Buffered C Powder

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/05/2022
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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 collagen formation  
Maintain/support natural liver cleansing/detoxification processes  
Maintain/support energy production  
Maintain/support healthy eye function  
Maintain/support eye health  
Maintain/support healthy eyesight/vision  
Maintain/support healthy growth and development  
Maintain/support general health and wellbeing  
Maintain/support healthy teeth  
Maintain/support connective tissue health  
Aid/assist/helps connective tissue production/formation  
Maintain/support bone health  
Helps maintain/support joint cartilage health  
Maintain/support cardiovascular system health  
Maintain/support healthy cardiovascular system function  
Maintain/support blood capillary health  
Maintain/support healthy thyroid gland function  
Maintain/support healthy thyroid hormones  
Aid/assist thyroid hormone production  
Maintain/support bile production  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support immune system to fight illness  
Aid/assist/helps protein synthesis in the body  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)

Public Summary



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

Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
Aid/assist/helps synthesis of (insert vitamin) in the body  
Support healthy stress response in the body  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system function  
Maintain/support skin integrity/structure  
Maintain/support wound healing in healthy individuals  
Maintain/support skin repair/healing/regeneration

#### Indication Requirements

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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).

Label statement: Vitamins can only be of assistance if the dietary vitamin intake is inadequate OR Vitamin supplements should not replace a balanced diet.

Product presentation must not imply or refer to any thyroid related diseases.

Product presentation must not imply or refer to serious immunological diseases.

If product is indicated for supplementation, 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 mental illnesses, disorders or conditions.

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

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 bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

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

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

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 any form of arthritis or osteoarthritis unless qualified as mild.

Product presentation must only refer to detoxification in relation to natural body processes.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

#### Additional Product information

#### Pack Size/Poison information

Pack Size	Poison Schedule
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#### Components

##### 1. Formulation 1

Dosage Form	Powder, oral
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Route of Administration	Oral
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#### Visual Identification

#### Active Ingredients

alpha lipoic acid	12.5 mg/g
ascorbic acid	390 mg/g
betacarotene	1 mg/g



Australian Government  
Department of Health  
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<b>calcium ascorbate dihydrate</b>	<b>125 mg/g</b>
Equivalent: ascorbic acid	102.7 mg/g
Equivalent: calcium	11.75 mg/g
<b>d-alpha-tocopheryl acid succinate</b>	<b>17 mg/g</b>
Equivalent: d-alpha-tocopherol	20.57 IU/g
<b>hesperidin</b>	<b>25 mg/g</b>
<b>magnesium ascorbate monohydrate</b>	<b>25 mg/g</b>
Equivalent: magnesium	1.55 mg/g
Equivalent: ascorbic acid	22.18 mg/g
<b>rutoside</b>	<b>25 mg/g</b>
<b>sodium ascorbate</b>	<b>125 mg/g</b>
Equivalent: sodium	14.5 mg/g
Equivalent: ascorbic acid	110.5 mg/g
<b>zinc citrate dihydrate</b>	<b>5 mg/g</b>
Equivalent: zinc	1.61 mg/g

#### Other Ingredients (Excipients)

Acacia  
citric acid  
colloidal anhydrous silica  
Flavour  
Pea Starch  
purified water  
sodium alginate  
sodium bicarbonate  
Stevia rebaudiana

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Public Summary