



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

## Public Summary

|                                |                                                     |                      |
|--------------------------------|-----------------------------------------------------|----------------------|
| <b>Summary for ARTG Entry:</b> | 299281                                              | Orthoplex Clinical C |
| <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<br>Australia |                      |
| <b>ARTG Start Date</b>         | 2/02/2018                                           |                      |
| <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 Clinical C

|                     |                         |                       |            |
|---------------------|-------------------------|-----------------------|------------|
| <b>Product Type</b> | Single Medicine Product | <b>Effective Date</b> | 21/12/2021 |
|---------------------|-------------------------|-----------------------|------------|

### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Helps reduce/decrease free radical damage to body cells  
Maintain/support collagen formation  
Aids/assists natural body cleansing/detoxification processes  
Maintain/support natural body cleansing/detoxification processes  
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 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  
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 blood capillary health  
Maintain/support healthy thyroid gland function  
Maintain/support healthy thyroid hormones  
Aid/assist thyroid hormone production  
Maintain/support bile production

Public Summary



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

Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support immune system to fight illness  
Helps decrease/reduce homocysteine levels in healthy individuals  
Aid/assist/helps protein synthesis in the body  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in athletes  
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)  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system health  
Maintain/support nervous system function  
Maintain/support reproductive system health  
Maintain/support healthy reproductive hormones in healthy males  
Maintain/support sperm production  
Maintain/support skin health  
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 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 vision correction, faults or serious eye disease e.g. macular degeneration.  
Product presentation must not imply or refer to any thyroid related 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 drugs/alcohol.  
Product presentation must only refer to detoxification in relation to natural body processes.  
Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.  
Product presentation must not imply or refer to serious immunological diseases.  
Label statement: If symptoms persist, talk to your health professional.  
Product presentation must not imply or refer to infertility.  
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 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 circulatory disorders/diseases/conditions e.g. thrombosis.  
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 hormone imbalances.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

Not recommended for use by pregnant and lactating women (or words to that effect).  
The recommended daily dose of this medicine contains [state quantity and units] of sodium (or words to that effect).  
Adults only.  
This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

#### Additional Product information



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**Department of Health**  
Therapeutic Goods Administration

**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**

|                                          |                     |
|------------------------------------------|---------------------|
| <b>alpha lipoic acid</b>                 | <b>20 mg</b>        |
| <b>calcium ascorbate dihydrate</b>       | <b>726.39 mg</b>    |
| Equivalent: ascorbic acid                | 600 mg              |
| <b>glutathione</b>                       | <b>10 mg</b>        |
| <b>hesperidin</b>                        | <b>25 mg</b>        |
| <b>nicotinamide</b>                      | <b>5 mg</b>         |
| <b>palm tocotrienols complex</b>         | <b>2.001 mg</b>     |
| <b>pyridoxal 5-phosphate monohydrate</b> | <b>2.19 mg</b>      |
| Equivalent: pyridoxine                   | 1.5 mg              |
| <b>rutoside</b>                          | <b>25 mg</b>        |
| <b>selenomethionine</b>                  | <b>38 microgram</b> |
| Equivalent: selenium                     | 15 microgram        |
| <b>sodium ascorbate</b>                  | <b>452.49 mg</b>    |
| Equivalent: ascorbic acid                | 400 mg              |

**Other Ingredients (Excipients)**

ascorbyl palmitate  
calcium hydrogen phosphate dihydrate  
Carnauba Wax  
colloidal anhydrous silica  
croscarmellose sodium  
hypromellose  
macrogol 400  
microcrystalline cellulose  
Palm Fruit Oil  
starch sodium octenyl succinate

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Public Summary