



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	306693	Orthoplex Zinc Citrate
<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>	5/07/2018	
<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 Zinc Citrate**

Product Type	Single Medicine Product	Effective Date	6/11/2020
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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 eye health
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support smell sensation
- Maintain/support taste sensation
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps protein synthesis in the body
- 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 nervous system health
- Maintain/support nervous system function
- Maintain/support female reproductive system health
- Maintain/support reproductive system health
- Maintain/support healthy reproductive hormones
- Maintain/support sperm production
- Maintain/support skin health
- Maintain/support skin integrity/structure
- Maintain/support skin repair/healing/regeneration in healthy individuals

**Indication Requirements**

- Product presentation must not imply or refer to infertility.
- 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 mental illnesses, disorders or conditions.

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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 serious immunological diseases.

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**

If symptoms persist consult your healthcare practitioner (or words to that effect).

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.

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**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

**zinc citrate dihydrate** **95.8 mg**

Equivalent: zinc 30 mg

**Other Ingredients (Excipients)**

colloidal anhydrous silica

disodium edetate

gellan gum

glycine

hypromellose

leucine

potable water

potassium acetate

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