



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

## Public Summary

|                                |   |                             |
|--------------------------------|---|-----------------------------|
| <b>Summary for ARTG Entry:</b> | 206285  | Orthoplex BioOmega Capsules |
| <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>         | 21/02/2013  |                             |
| <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 BioOmega Capsules

| Product Type | Single Medicine Product | Effective Date | 22/10/2020 |
|--------------|-------------------------|----------------|------------|
|--------------|-------------------------|----------------|------------|

### Permitted Indications

- Helps maintain/support healthy eye development
- Maintain/support healthy eye function
- Maintain/support eye health
- Helps maintain/support eye retina health
- Helps maintain/support healthy vision development
- Maintain/support general health and wellbeing
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Support healthy stress response in the body
- Maintain/support cognitive development
- Maintain/support cognitive function/mental function
- Maintain/support general mental wellbeing
- Maintain/support brain function
- Maintain/support brain health
- Maintain/support nervous system health
- Maintain/support brain/central nervous system development
- Maintain/support nervous system function
- Support healthy emotional/mood balance

### Indication Requirements

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

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 neurological conditions or developmental delays.

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 serious cardiovascular conditions.



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

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.  
If symptoms persist, seek the advice of a healthcare professional.

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, soft

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

|  |                |
|--|----------------|
| <b>natural fish oil</b>                  | <b>1000 mg</b> |
| Equivalent: docosahexaenoic acid         | 120 mg         |
| Equivalent: eicosapentaenoic acid        | 180 mg         |
| Equivalent: omega-3 marine triglycerides | 300 mg         |

**Other Ingredients (Excipients)**

**d-alpha-tocopherol**

**Gelatin**

**glycerol**

**Peppermint Oil**

**purified water**

**Soya Oil**

**Spearmint oil**

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary