



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	206285	Orthoplex BioOmega Capsules
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	21/02/2013	
Product Category	Medicine	
Status	Active	
Approval Area	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
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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 vision correction, faults or serious eye disease e.g. macular degeneration.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to neurological conditions or developmental delays.

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).



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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

natural fish oil	1000 mg
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

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