



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

## Public Summary

<b>Summary for ARTG Entry:</b>	337185	Clinical Lipids 2:1
<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>	28/05/2020	
<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 . Clinical Lipids 2:1

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	20/06/2022
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### Permitted Indications

Helps maintain/support eye retina health  
Maintain/support healthy eyesight/vision  
Maintain/support general health and wellbeing  
Anti-inflammatory/relieve inflammation in healthy individuals  
Maintain/support cardiovascular system health  
Helps maintain/support healthy heart function  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy individuals  
Maintain/support cognitive function/mental function  
Maintain/support learning and information processing  
Maintain/support memory/mental recall  
Maintain/support brain function  
Maintain/support nervous system health  
Maintain/support nervous system function  
Support healthy emotional/mood balance  
Helps maintains/support healthy foetal CNS/brain development  
Maintains/support healthy foetal development  
Maintain/support healthy pregnancy  
Maintain/support maternal health

### 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 mental illnesses, disorders or conditions.  
Product presentation must not imply or refer to serious cardiovascular conditions.  
If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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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Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.

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).

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

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

No Warnings included on Record

#### 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>concentrated fish Omega-3 triglycerides</b>	<b>1.34 g</b>
Equivalent: eicosapentaenoic acid	670 mg
Equivalent: docosahexaenoic acid	335 mg

##### Other Ingredients (Excipients)

**d-alpha-tocopherol**

**Gelatin**

**glycerol**

**Lemon Oil Distilled**

**purified water**

**Sunflower Oil**

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