



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

## Public Summary

<b>Summary for ARTG Entry:</b>	311638	BioActive Lipids
<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>	16/11/2018	
<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 . BioActive Lipids

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	23/11/2021
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### Permitted Indications

Helps maintain/support healthy eye development  
Helps maintain/support healthy eye development in children  
Maintain/support healthy eye function  
Maintain/support eye health  
Helps maintain/support eye retina health  
Helps maintain/support healthy vision development in children  
Helps maintain/support healthy vision development  
Maintain/support healthy growth and 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 in children  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in athletes  
Maintain/support (state vitamin/mineral/nutrient) levels in the body in healthy individuals  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Support healthy stress response in the body in children  
Support healthy stress response in the body  
Support healthy stress response in the body in elderly individuals  
Maintain/support cognitive development in children  
Maintain/support cognitive development  
Maintain/support cognitive function/mental function in children  
Maintain/support cognitive function/mental function in elderly individuals  
Maintain/support cognitive function/mental function  
Maintain/support memory/mental recall in elderly individuals  
Maintain/support memory/mental recall  
Maintain/support general mental wellbeing  
Maintain/support brain function

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- Maintain/support brain function in elderly individuals
- Maintain/support brain function in children
- Maintain/support brain health in children
- Maintain/support brain health
- Maintain/support brain health in elderly individuals
- Maintain/support nervous system health
- Maintain/support brain/central nervous system development
- Maintain/support brain/central nervous system development in children
- Maintain/support nervous system function
- Support healthy emotional/mood balance
- Support healthy emotional/mood balance in elderly individuals
- Support healthy emotional/mood balance in children
- Helps maintains/support healthy foetal CNS/brain development
- Maintains/support healthy foetal development
- Maintain/support healthy pregnancy
- Maintain/support maternal health
- Maintain/support sperm 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.
- 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 you are concerned about the health of yourself or your baby, talk to your health practitioner.
- Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
- Product presentation must not imply or refer to neurological conditions or developmental delays.
- Product presentation must not imply or refer to infertility.
- Label statement: If symptoms persist, talk to your health professional.
- 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.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

- If symptoms persist, seek the advice of a healthcare professional.
- 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.

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Capsule, soft
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>concentrated fish Omega-3 triglycerides</b>	<b>1000 mg</b>
Equivalent: eicosapentaenoic acid	360 mg
Equivalent: docosahexaenoic acid	240 mg

**Other Ingredients (Excipients)**

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**d-alpha-tocopherol**  
**Gelatin**  
**glycerol**  
**Lemon Oil Distilled**  
**purified water**  
**Sunflower Oil**

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