



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

## Public Summary

<b>Summary for ARTG Entry:</b>	322581	Fish Oil
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	JSHealth Vitamins Pty Ltd	
<b>Postal Address</b>	31 Knox Street, Double Bay, Sydney, NSW, 2028 Australia	
<b>ARTG Start Date</b>	2/09/2019	
<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 . Fish Oil

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	17/11/2022
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### Permitted Indications

Maintain/support eye health  
Maintain/support general health and wellbeing  
Anti-inflammatory/relieve inflammation  
Decrease/reduce/relieve mild joint pain/soreness  
Decrease/reduce/relieve mild joint stiffness  
Helps maintain/support healthy cholesterol  
Maintain/support healthy cardiovascular system function  
Maintain/support heart health  
Help maintain/support emotional wellbeing  
Maintain/support cognitive function/mental function  
Maintain/support general mental wellbeing  
Maintain/support brain function  
Decrease/reduce/relieve symptoms of mild eczema/dermatitis  
Maintain/support skin health

### Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.  
Product presentation must not imply or refer to serious cardiovascular conditions.  
Product presentation must only refer to mild joint symptoms.  
Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.  
Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must only refer to mild eczema.

Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

### Standard Indications



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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>1.5 g</b>
Equivalent: docosahexaenoic acid	360 mg
Equivalent: eicosapentaenoic acid	540 mg

**Other Ingredients (Excipients)**

**d-alpha-tocopherol**

**Flavour**

**Gelatin**

**glycerol**

**purified water**

**Soya Oil**

**vanillin**

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