



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

## Public Summary

<b>Summary for ARTG Entry:</b>	94756	Fish Oil 1000
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Herbs of Gold Pty Ltd	
<b>Postal Address</b>	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
<b>ARTG Start Date</b>	10/06/2003	
<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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 1000

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	1/10/2019
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### Permitted Indications

Helps maintain/support healthy eye development  
Helps maintain/support healthy eye development in breast fed healthy infants  
Maintain/support eye health in breast fed healthy infants  
Maintain/support eye health  
Helps maintain/support eye retina health in breast fed healthy infants  
Helps maintain/support eye retina health  
Maintain/support healthy growth and development in breast fed healthy infants  
Maintain/support general health and wellbeing  
Anti-inflammatory/relieve inflammation  
Maintain/support joint health  
Maintain/support healthy blood circulation  
Maintain/support cardiovascular system health  
Maintain/support healthy cardiovascular system function  
Maintain/support heart health  
Maintain/support muscle health  
Maintain/support muscle function  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Maintain/support cognitive function/mental function  
Maintain/support brain function

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Maintain/support brain function in breast fed healthy infants  
Maintain/support brain health  
Maintain/support nervous system health  
Maintain/support brain/central nervous system development  
Maintain/support nervous system function  
Decrease/reduce/relieve menstruation pain/dysmenorrhoea  
Maintains/support healthy foetal development  
Maintain/support skin 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.

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

Product presentation must not imply or refer to serious cardiovascular conditions.

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.

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).

If directed to women, 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.

#### 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
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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>natural fish oil</b>	<b>1 g</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**  
**purified water**  
**Soya Oil**

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