



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	194153	Fish Oil 1700
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	26/01/2012	
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 . Fish Oil 1700

Product Type	Single Medicine Product	Effective Date	16/11/2020
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Permitted Indications

Helps maintain/support healthy eye development in breast fed healthy infants

Helps maintain/support healthy eye development

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 in breast fed healthy infants

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

Decrease/reduce/relieve menstruation pain/dysmenorrhoea

Maintains/support healthy foetal development

Maintain/support skin health

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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 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 not imply or refer to mental illnesses, disorders or conditions.

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

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

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).

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

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

natural fish oil	1.7 g
Equivalent: docosahexaenoic acid	204 mg
Equivalent: eicosapentaenoic acid	306 mg

Other Ingredients (Excipients)

d-alpha-tocopherol

Flavour

Gelatin

glycerol

purified water

Soya Oil

vanillin

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