



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	366350	FISH OIL HEALTH & HEART
ARTG entry for	Medicine Listed	
Sponsor	Melrose Laboratories Pty Ltd	
Postal Address	16-18 Lionel Rd, Mt Waverley, VIC, 3149 Australia	
ARTG Start Date	18/05/2021	
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 HEALTH & HEART

Product Type	Single Medicine Product	Effective Date	24/11/2021
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Permitted Indications

- Helps maintain/support healthy eye development in children up to 12 years of age
- Helps maintain/support healthy eye development
- Maintain/support healthy eye function
- Maintain/support eye health
- Helps maintain/support eye retina health
- Helps maintain/support healthy vision development
- Maintain/support healthy eyesight/vision in children up to 12 years of age
- Maintain/support general health and wellbeing
- Helps in the maintenance of healthy blood lipids/blood fats
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support cognitive function/mental function
- Maintain/support brain function
- Maintain/support nervous system health
- Maintain/support brain/central nervous system development in children up to 12 years of age
- Maintain/support brain/central nervous system development
- Maintain/support nervous system function
- Maintains/support healthy foetal development

Indication Requirements

- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to neurological conditions or developmental delays.
- 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 lowering blood lipids, blood fats and triglycerides.
- Product presentation must not imply or refer to serious cardiovascular conditions.



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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.

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

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

natural fish oil	902 mg/mL
Equivalent: eicosapentaenoic acid	162.4 mg/mL
Equivalent: omega-3 marine triglycerides	316 mg/mL
Equivalent: docosahexaenoic acid	108.2 mg/mL

Other Ingredients (Excipients)

d-alpha-tocopheryl acetate

Flavour

Lemon Oil

Rosemary Oil

Stevia rebaudiana

Sunflower Oil

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