



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	307903	Melrose Omega Fish Oil + Vitamin D
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Melrose Laboratories Pty Ltd	
<b>Postal Address</b>	16-18 Lionel Rd, Mt Waverley, VIC, 3149 Australia	
<b>ARTG Start Date</b>	7/08/2018	
<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 . Melrose Omega Fish Oil + Vitamin D**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	26/11/2020
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**Permitted Indications**

- 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
- Maintain/support general health and wellbeing
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building in children
- Aids/assists healthy bone development/growth/building in healthy infants
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- 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
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle function
- Maintain/support healthy neuromuscular system/function
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in elderly individuals
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support cognitive function/mental function

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Maintain/support brain function  
 Maintain/support nervous system health  
 Maintain/support brain/central nervous system development  
 Maintain/support nervous system function  
 Maintains/support healthy foetal development

**Indication Requirements**

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

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 serious immunological diseases.

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.

Product presentation must not imply or refer to neurological conditions or developmental delays.

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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 serious cardiovascular conditions.

Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.

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

**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**

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

**1 . Formulation 1**

<b>Dosage Form</b>	Oral Liquid
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>colecalfiferol</b>	<b>5 microgram/mL</b>
<b>natural fish oil</b>	<b>912 mg/mL</b>
Equivalent: eicosapentaenoic acid	164 mg/mL
Equivalent: omega-3 marine triglycerides	318.8 mg/mL
Equivalent: docosahexaenoic acid	109.2 mg/mL

**Other Ingredients (Excipients)**

**d-alpha-tocopheryl acetate**  
**dl-alpha-tocopherol**  
**Flavour**  
**Lemon Oil**  
**medium chain triglycerides**  
**Sunflower Oil**

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