



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	307901	Melrose Omega Cod Liver Oil
ARTG entry for	Medicine Listed	
Sponsor	Melrose Laboratories Pty Ltd	
Postal Address	16-18 Lionel Rd, Mt Waverley, VIC, 3149 Australia	
ARTG Start Date	7/08/2018	
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.

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 . Melrose Omega Cod Liver Oil

Product Type	Single Medicine Product	Effective Date	16/08/2018
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Permitted Indications

- Maintain/support healthy eye function
- Maintain/support eye health
- Helps maintain/support eye retina health
- Maintain/support healthy eyesight/vision
- Maintain/support body mucous membrane health
- Maintain/support general health and wellbeing
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building in healthy infants
- Aids/assists healthy bone development/growth/building in children
- 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
- Maintain/support healthy cardiovascular system function
- 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 when sun exposure is inadequate

Public Summary



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Department of Health
 Therapeutic Goods Administration

Maintain/support (state vitamin/mineral/nutrient) levels in the body
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in elderly individuals
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when sun exposure is inadequate
 Maintain/support cognitive function/mental function
 Maintain/support brain function
 Maintain/support skin health
 Maintain/support skin integrity/structure

Indication Requirements

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.

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

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 serious cardiovascular conditions.

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 serious musculoskeletal or neurological conditions.

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral

Visual Identification

Active Ingredients

Cod-liver oil	924 mg/mL
Equivalent: colecalciferol	0 microgram/mL
Equivalent: docosahexaenoic acid	83.2 mg/mL
Equivalent: vitamin A	0 RE/millilitre
Equivalent: omega-3 marine triglycerides	161.6 mg/mL
Equivalent: eicosapentaenoic acid	74 mg/mL
colecalciferol	2 microgram/mL
retinol palmitate	342 microgram/mL
Equivalent: vitamin A	187.6 RE/millilitre

Other Ingredients (Excipients)

Public Summary



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dl-alpha-tocopherol
Flavour
medium chain triglycerides

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