



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	315876	BioClean Omega Triple
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Medlab Pty Ltd	
<b>Postal Address</b>	PO Box 6452, ALEXANDRIA, NSW, 2015 Australia	
<b>ARTG Start Date</b>	28/03/2019	
<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 . BioClean Omega Triple**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	28/03/2019
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**Permitted Indications**

- Helps maintain/support healthy eye development
- Helps maintain/support healthy vision development
- Maintain/support healthy growth and development
- Decrease/reduce/relieve mild joint aches and pains
- Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis
- Helps enhance/improve/promote joint mobility
- Decrease/reduce/relieve mild joint stiffness
- Helps in the maintenance of healthy blood lipids/blood fats
- Maintain/support cardiovascular system health
- Maintain/support cognitive function/mental function
- Maintain/support general mental wellbeing
- Maintain/support brain/central nervous system development

**Indication Requirements**

- Product presentation must only refer to mild joint symptoms.
- 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.
- Label statement: If symptoms persist, talk to your health professional.

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Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

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

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 lowering blood lipids, blood fats and triglycerides.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

If symptoms persist consult your healthcare practitioner (or words to that effect).

**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, enteric

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>concentrated fish Omega-3 triglycerides</b>	<b>975 mg</b>
Equivalent: eicosapentaenoic acid	650 mg
Equivalent: docosahexaenoic acid	260 mg

**Other Ingredients (Excipients)**

Gelatin

glycerol

pectin

purified water

sorbitol

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