Public Summary

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

Product Type	Single Medicine Product	**Effective Date**	28/03/2019

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 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 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 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 any form of arthritis or osteoarthritis unless qualified as mild.

Product presentation must only refer to mild joint symptoms.

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

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

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, enteric
Route of Administration	Oral
Visual Identification	

Active Ingredients

concentrated fish Omega-3 triglycerides	**975 mg**
Equivalent: eicosapentaenoic acid	650 mg
Equivalent: docosahexaenoic acid	260 mg

Other Ingredients (Excipients)

Gelatin
glycerol
pectin
purified water
sorbitol

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