



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

## Public Summary

<b>Summary for ARTG Entry:</b>	317128	Mediherb Omega 3 Clean Essentials
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	2/05/2019	
<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.

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 . Mediherb Omega 3 Clean Essentials

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	25/03/2020
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### Permitted Indications

- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in breastfeeding women
- Anti-inflammatory/relieve inflammation
- 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 cognitive function/mental function
- Maintain/support brain function
- Maintain/support brain health

### Indication Requirements

- 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.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings

For practitioner dispensing only.



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If symptoms persist, seek the advice of a healthcare professional.

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, soft

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>concentrated fish Omega-3 triglycerides</b>	<b>1000 mg</b>
Equivalent: eicosapentaenoic acid	400 mg
Equivalent: docosahexaenoic acid	200 mg

**Other Ingredients (Excipients)**

**Flavour**

**Gelatin**

**glycerol**

**mixed (low-alpha type) tocopherols concentrate**

**purified water**

**vanillin**

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