



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

## Public Summary

<b>Summary for ARTG Entry:</b>	265518	ETHICAL NUTRIENTS HIGH STRENGTH OMEGA-3
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	7/12/2015	
<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 . ETHICAL NUTRIENTS HIGH STRENGTH OMEGA-3

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	6/04/2021
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#### Permitted Indications

- Maintain/support eye health
- Maintain/support general health and wellbeing
- Anti-inflammatory/relieve inflammation
- Traditionally used in Naturopathic medicine to decrease/reduce/relieve mild rheumatic aches and pains
- Helps in the maintenance of healthy blood lipids/blood fats
- Maintain/support cardiovascular system health
- Maintain/support heart health
- Maintain/support cognitive function/mental function
- Maintain/support nervous system function
- Maintains/support healthy foetal development
- Maintain/support healthy pregnancy

#### Indication Requirements

- 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 mental illnesses, disorders or conditions.
- 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 bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must only refer to mild rheumatic aches/pains.
- 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



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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, soft

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>concentrated fish Omega-3 triglycerides</b>	<b>1.2 g</b>
Equivalent: eicosapentaenoic acid	463 mg
Equivalent: docosahexaenoic acid	231 mg

**Other Ingredients (Excipients)**

d-alpha-tocopherol

Flavour

Gelatin

glycerol

purified water

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