



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

## Public Summary

<b>Summary for ARTG Entry:</b>	387377	Nordic Naturals Omega-3
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Nordic Naturals Australasia Pty Ltd	
<b>Postal Address</b>	PO Box 4130, DONCASTER HEIGHTS, VIC, 3109 Australia	
<b>ARTG Start Date</b>	22/04/2022	
<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 . Nordic Naturals Omega-3

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	22/04/2022
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#### Permitted Indications

Maintain/support general health and wellbeing

#### Indication Requirements

No Indication Requirements included on Record

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

No Warnings included on Record

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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#### Components

##### 1 . Formulation 1

<b>Dosage Form</b>	Capsule, soft
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<b>Route of Administration</b>	Oral
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#### Visual Identification

#### Active Ingredients

<b>natural fish oil</b>	<b>1.0105 g</b>
Equivalent: docosahexaenoic acid	120 mg
Equivalent: eicosapentaenoic acid	180 mg

#### Other Ingredients (Excipients)

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**Gelatin**

**glycerol**

**Lemon Oil**

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

**purified water**

**Rosemary Oil**

**Sunflower Oil**

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