



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	340744	Nordic Naturals ProOmega
ARTG entry for	Medicine Listed	
Sponsor	Nordic Naturals Australasia Pty Ltd	
Postal Address	PO Box 4130, DONCASTER HEIGHTS, VIC, 3109 Australia	
ARTG Start Date	3/08/2020	
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.

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 . Nordic Naturals ProOmega

Product Type	Single Medicine Product	Effective Date	3/08/2020
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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

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, soft
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Route of Administration	Oral
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Visual Identification

Active Ingredients

natural fish oil	1.05 g
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Equivalent: docosahexaenoic acid	225 mg
Equivalent: eicosapentaenoic acid	325 mg
Equivalent: omega-3 marine triglycerides	90 mg

Other Ingredients (Excipients)

Gelatin

glycerol

Lemon Oil

mixed (high-alpha type) tocopherols concentrate

purified water

Rosemary Oil

Sunflower Oil

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