



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	171612	South Pacific Omega 3 Fish Oil
ARTG entry for	Medicine Listed (Export Only)	
Sponsor	B & N Global Pty Ltd	
Postal Address	6/108 Ballandella Road, PENDLE HILL, NSW, 2145 Australia	
ARTG Start Date	24/05/2010	
Product Category	Medicine	
Status	Active	
Approval Area	Export only Medicines	

Conditions

Except where the sponsor has been contracted by an overseas party to manufacturer the goods and that party will be responsible for placing the goods on the market in countries other than Australia, the sponsor must have and shall retain, while the goods remain listed, evidence necessary to substantiate and support the accuracy of the indications in relation to the listed goods, and upon the request of the Head, Office of Prescription Medicines Authorisation Branch, Therapeutic Goods Administration, shall produce such evidence to this officer.

The conditions applying to these goods when they are exported from Australia are given below:

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No. 8 and condition No. 9.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995, other than condition No.11

The sponsor shall hold stability data to support the claimed shelf life of the listed medicine according to the labelled storage conditions except where: (i) each overseas importer accepts responsibility for holding stability data for this product; (ii) the sponsor has a written agreement to this effect from each overseas importer; and (iii) the sponsor retains copies of all such agreements while the medicine remains listed on the ARTG.

This product must not be supplied for sale in Australia, including supply via duty free outlets.

Products

1 . South Pacific Omega 3 Fish Oil

Product Type	Single Medicine Product	Effective Date	24/05/2010
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

- * RHAR ? Temporary relief of the pain of rheumatoid arthritis.
- * RHEUM ? Temporary relief of the pain of rheumatism OR Temporary relief of rheumatic pain.
- * RHEUM2 ? Symptomatic relief of rheumatism.
- * ARTH2 - May help reduce joint inflammation associated with arthritis.
- * ARTH3 - May help reduce joint swelling associated with arthritis.
- * ARTH4 ? May help increase joint mobility associated with arthritis.
- * RHEUM4 ? May assist in the management of rheumatism.
- * ARTH1 - For the relief of pain of arthritis OR Temporary relief of arthritic pain.
- * Supports the health of the joints.
- * Supports healthy joint function.
- * Assists in maintaining joint mobility.
- * Provides an anti-inflammatory action within the body which may help reduce inflammation and joint swelling associated with arthritis.
- * SKIN1 ? For the symptomatic relief of eczema.
- * SKIN9 ? May assist in the management of eczema.
- * Maintains healthy skin.
- * SKIN10 ? May assist in the management of psoriasis.
- * SKIN11 ? May assist in the management of dermatitis.
- * SKIN12 ? May assist in the management of dry skin.
- * SKIN2 ? For the symptomatic relief of psoriasis.
- * SKIN3 ? For the symptomatic relief of dermatitis.
- * SKIN4 ? For the symptomatic relief of dry skin.
- * Supports/maintains the health of the cardiovascular system.
- * Omega 3 fatty acids are important for cardiovascular health.



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- * Maintains the health of the heart.
- * Maintains normal healthy brain function.
- * Supports brain health.
- * Supports the maintenance of healthy mood.
- * Helps to maintain healthy cognitive function.
- * May help maintain healthy (and or normal) cholesterol levels.
- * May help to maintain cholesterol levels within the normal (and or healthy) range and improve HDL:LDL ratio.
- * Maintains normal healthy nervous system.
- * A natural source of marine omega 3 fatty acids.
- * Omega 3 fatty acids are very important as the body cannot produce them and they can therefore only obtain them from the diet.
- * Polyunsaturated fatty acids, such as those found in fish oil, are used in the body in the manufacture of prostaglandins.
- * The essential fatty acids in fish oil are essential for the healthy function of the eye.
- * Well ? Aids, assists or helps in the maintenance or improvement of general wellbeing.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded				

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 .

Dosage Form	Capsule, soft
Route of Administration	Oral
Visual Identification	20 minim oblong clear transparent softgel capsule containing pale yellow oily liquid.

Active Ingredients

natural fish oil	1000 mg
Equivalent: omega-3 marine triglycerides	300 mg
Equivalent: eicosapentaenoic acid	180 mg
Equivalent: docosahexaenoic acid	120 mg

Other Ingredients (Excipients)

d-alpha-tocopherol
Gelatin
glycerol
purified water

Public Summary

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