

## PROFESSIONAL INFORMATION

### SCHEDULING STATUS:

To be allocated.

### PROPRIETARY NAME AND DOSAGE FORM:

**Omega 3 Fish Oil 1000mg** (capsules).

### COMPOSITION (per capsule):

<b>Ingredients:</b>	
Natural Fish Oil	1000mg
<b>Containing Omega 3:</b>	
Eicosapentaenoic Acid (EPA)	180mg
Docosahexaenoic Acid (DHA)	120mg
Vitamin E	1mg

This product is not suitable for vegans and vegetarians. (Sugar Free)

### PHARMACOLOGICAL CLASSIFICATION:

Category D (Complementary Medicine) – Health Supplement.  
This medicine has not been evaluated by SAHPRA for its quality, safety and intended use.

### PHARMACOLOGICAL ACTION

#### PHARMACOKINETICS:

**Omega 3 Fish Oil 1000mg** contains Natural Fish Oil which is high in Omega 3 fatty acids (EPA, DHA) and Vitamin E on which pharmacokinetic studies have not been conducted.

#### PHARMACODYNAMICS:

**Omega 3 Fish Oil 1000mg** has shown to be beneficial for cardiac and nervous system health.

It contains essential Omega 3 fatty acids; EPA and DHA which have shown to exert an anti-inflammatory effect.

#### INDICATIONS:

**Omega 3 Fish Oil 1000mg** is a supplement which helps to maintain the cardiovascular system while supporting cognitive function and brain health.

#### CONTRAINDICATIONS:

This product should not be taken by individuals who have disturbances in calcium metabolism (hypercalcaemia). Do not use if a known hypersensitivity or allergy exists towards any of the ingredients. This product should be avoided in individuals who are allergic to shellfish. If in doubt, consult your medical practitioner

#### WARNINGS AND SPECIAL PRECAUTIONS:

**Omega 3 Fish Oil 1000mg** should be used with caution in individuals who are on anticoagulant/antiplatelet treatment, haemophiliac or undergoing surgery due to its anticoagulant effect. It should also be used with caution in individuals who have renal insufficiency. Should your general health worsen, or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or healthcare professional for advice. Do not exceed the recommended daily dosage. Do not use after the expiry date.

#### INTERACTIONS:

If you are taking any chronic medication, do not use this product without consulting your medical practitioner.

Anticoagulant/Antiplatelet Medication: If taken concomitantly with natural fish oil as in **Omega 3 Fish Oil 1000mg**, it may potentiate the anticoagulant effect.

Antihypertensives: Medication: If taken concomitantly with natural fish oil as in **Omega 3 Fish Oil 1000mg**, it may potentiate a hypotensive effect.

Calcium Modulating Medication: If taken concomitantly with natural fish oil as in **Omega 3 Fish Oil 1000mg**, it may affect calcium levels in the body.

#### PREGNANCY AND BREASTFEEDING:

Although regarded as safe, consult your healthcare professional before use in pregnancy and breastfeeding.

#### DOSAGE AND DIRECTIONS FOR USE:

Always tell your healthcare professional if you are taking any other medicine.

Adults: 1 to 3 capsules daily with food or as professionally advised.

Children: 1 to 2 capsules daily with food or as professionally advised.

#### SIDE EFFECTS:

##### Blood & Lymphatic System Disorders:

Frequency unknown: Anticoagulant effect.

##### Gastrointestinal System Disorders:

Frequency unknown: Possible indigestion, however this product generally is associated with low reflux, Nausea.

##### Immune System Disorders:

Frequency unknown: Hypersensitivity reactions.

#### KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT:

In the event of overdose, consult your doctor, pharmacist or healthcare professional. If neither is available, contact your nearest hospital or poison centre. Treatment is symptomatic and supportive.

#### IDENTIFICATION:

Transparent yellow, oblong soft gelatine capsule.

#### PRESENTATION:

70/150/400 capsules in a white bottle with an induction seal and a plastic tamperproof lid.

#### STORAGE INSTRUCTIONS:

Store below 30°C in a dry place.  
KEEP OUT OF REACH OF CHILDREN

**REGISTRATION NUMBER:**

To be allocated.

**NAME AND BUSINESS ADDRESS OF APPLICANT:**

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**DATE OF REGISTRATION**

To be confirmed

**CATEGORY**

Category D (Complementary Medicine) – Health Supplement.  
This medicine has not been evaluated by SAHPRA for its quality, safety and intended use.

Good Health Products Pty Ltd

**REFERENCES**

1. WebMD (n.d), Fish Oil, WebMD, viewed 13 April 2020, <<https://www.webmd.com/vitamins/ai/ingredientmono-993/fish-oil>>
2. WebMD (n.d), Omega-3 Fish Oil Supplements for Heart Disease, WebMD, viewed 08 April 2020, <<https://www.webmd.com/hypertension-high-blood-pressure/guide/omega-3-fish-oil-supplements-for-high-blood-pressure>>