

PROFESSIONAL INFORMATION

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE: OMEGAGENICS EPA DHA 1000

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Serving Size	1 softgel
Servings Per Container: 60 pack size	60
Marine Lipid Concentrate [fish (sardine, anchovy, and mackerel) oil]	1.4 g
EPA (Eicosapentaenoic acid)	710 mg
DHA (Docosahexaenoic acid)	290 mg
Other Omega-3 Fatty Acids	100 mg

Other Ingredients: Marine lipid concentrate [fish (sardine, anchovy, and mackerel) oil], softgel shell (gelatin, glycerin, water), contains 2 percent or less of natural lemon flavour, natural lime flavour, mixed tocopherols (antioxidant), rosemary extract, and ascorbyl palmitate (antioxidant). Contains: Fish (sardine, anchovy, and mackerel).

For full list of excipients, see section 6.1

This product is non-GMO and gluten-free.

3. PHARMACEUTICAL FORM

Clear soft gelatin capsule containing a slightly yellow oil

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

OmegaGenics EPA-DHA 1000 features a concentrated, purified source of omega-3 fatty acids from sustainably sourced, cold-water fish. Each softgel provides a total of 710 mg EPA and 290 mg DHA. *

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4.2 Posology and method of administration

Take one softgels up to three times daily with food or as directed by your healthcare practitioner.

4.3 Contraindications

None known

4.4 Special warnings and precautions for use

Consult your healthcare practitioner if pregnant, nursing, or taking other nutritional supplements or medications. Keep out of the reach of children.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There are no adequate data from the use of **OmegaGenics EPA-DHA 1000** in pregnant or breast-feeding woman.

4.7 Effects on ability to drive and use machines

There are no adequate data from the use of **OmegaGenics EPA-DHA 1000** on the ability to drive and use machines.

4.8 Undesirable effects

None known.

4.9 Overdose

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category of medicine: D (Complementary Medicine)

Class of medicine: 34.13 Health supplements - Other

5.2 Pharmacokinetic properties

Pharmacokinetic studies have not been conducted on **OmegaGenics EPA-DHA 1000** product

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Contains 2 percent or less of natural lemon flavour and natural lime flavour
 Mixed tocopherols (antioxidant)
 Rosemary extract
 Ascorbyl palmitate (antioxidant)
 Softgel shell:
 Gelatin
 Glycerin
 Water

6.2 Incompatibilities

None known.

6.3 Shelf Life

24 Months.

6.4 Special precautions for storage

Keep tightly closed in a cool, dry place.
 Keep softgels in original container until required for use.
 KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Packs of 60 softgels in PET bottle with PET lid
 Pack-size: 60 softgels.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Amipro Advanced Development Products (pty) Ltd
 Unit 3 Eastgate Business Park, 1 South Road, Marlboro, Sandton, Johannesburg 2063
 Tel: 011 802 8101

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.