

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 300 ALGAE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Serving Size	2 softgels
Servings Per Container: 60 pack size	30
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Other Omega-3 Fatty Acids	600 mg
EPA (Eicosapentaenoic acid)	180 mg
DHA (Docosahexaenoic acid)	360 mg

Other Ingredients: Algal oil, softgel shell [water, modified corn starch, glycerin, carrageenan, sorbitol, caramel (colour), and beta-carotene (color)], sunflower oil, contains 2 percent or less of mixed tocopherols (antioxidant), natural flavour, sunflower lecithin, and ascorbyl palmitate (antioxidant).

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 reddish orange oil

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

OmegaGenics EPA-DHA 300 Algae features a concentrated, purified source of omega-3 fatty acids in triglyceride form from the microalgae *Schizochytrium* sp. Each softgel provides a sum of 300 mg EPA and DHA.*

* This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use. **OmegaGenics EPA-DHA 300 Algae** does not intend to prevent or cure any form of illness or disease and should not replace any medication. If you suffer from a chronic medical condition, consult your healthcare practitioner before using this product.

4.2 Posology and method of administration

Take two softgels up to two 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 300 Algae** 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 300 Algae** 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 300 Algae** product

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sunflower oil
Contains 2 percent or less of mixed tocopherols (antioxidant)
Natural flavour
Sunflower lecithin
Ascorbyl palmitate (antioxidant)
Softgel shell:
Modified corn starch
Carrageenan sorbitol
Caramel (colour)
Beta-carotene (colour)
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 amber glass bottles
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.