

PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S0**

Category D: Complementary medicine.

Discipline: Health Supplement

34.6 Fats, Oils and Fatty Acids



PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

OMGEAGENICS® ALGAE OMEGA-3S 2400 mg,

150 ML

COMPOSITION

Each two (2) softgel capsules of OMGEAGENICS® ALGAE OMEGA-3S contains the following actives:

Omega-3 Fatty Acids Triglycerides (from microalgae Schizochytrium sp.) (parts : whole)	600 mg
DHA (Docosahexaenoic acid triglyceride)	360 mg
EPA (Eicosapentaenoic acid triglyceride)	180 mg

Inactive Ingredients: Algal oil, ascorbyl palmitate (antioxidant), natural flavour, softgel shell [beta-carotene (colour), caramel (colour), carrageenan, glycerin, modified corn starch, sorbitol, water], sunflower oil, mixed tocopherols (antioxidant), and sunflower lecithin.

Contains Sugar: Sorbitol 76 mg

This product is suitable for Vegetarians, dairy & gluten free and non-GMO.

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

OMGEAGENICS® ALGAE OMEGA-3S helps to support cognitive health and brain function.

Features a concentrated, purified vegetarian source of omega-3 fatty acids from the microalgae Schizochytrium sp. Each softgel provides 300 mg of omega-3 in the triglyceride form.

Ingredients	Uses for ingredient
Omega-3 Fatty Acids Triglycerides	May help reduce triglycerides in the blood, which can lower the risk of cardiovascular disease. They are also known for their anti-inflammatory properties.
EPA (Eicosapentaenoic acid)	Getting more EPA in your diet has positive effects on coronary heart disease, high triglycerides (fats in the blood), high blood pressure, and inflammation
DHA (Docosahexaenoic acid)	Low levels are associated with an increased risk of heart disease, and some studies show that supplements reduce your risk.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **OMGEAGENICS® ALGAE OMEGA-3S** if you are hypersensitive (allergic) to any of the ingredients. Do not take this supplement if you have a fish or seafood allergy. If you have allergies, be sure to check with your healthcare professional before taking this supplement.

WARNING AND SPECIAL PRECAUTIONS

Should you have any of the following diagnosed conditions, consult with your healthcare professional before use: Bipolar disorder, Liver disease, Diabetes, Arrhythmia, Implanted defibrillator. If you are taking the following medication, please consult with your healthcare professional before taking: High blood pressure medication, Birth control pills, anticoagulants (Warfarin). If any of the following happens, stop using **OMGEAGENICS® ALGAE OMEGA-3S** and tell your doctor or go to the casualty department at your nearest hospital:

- Allergic reactions — rash, itching/swelling (especially of the face/tongue/throat), severe dizziness, trouble breathing;

These are all very serious effects. If you have them, you may have had a serious reaction to **OMGEAGENICS® ALGAE OMEGA-3S**. You may need urgent medical attention or hospitalisation.

Side effects that usually do not require medical attention (report to your healthcare professional if they continue):

- Stomach discomfort, Diarrhoea.

These are all very serious effects. If you have them, you may have had a serious reaction to **OMGEAGENICS® ALGAE OMEGA-3S**. You may need urgent medical attention or hospitalisation.

Seek advice from a health care practitioner if you have any medical condition. Discontinue use immediately should any adverse reaction occur.

Read this leaflet carefully because it contains important information for you. This product is available without a doctor's prescription.

- Keep this leaflet. You may need to read it again.
- Do not share medication with any other person.
- Ask your pharmacist if you need more information or advice.
- You must consult a doctor should your condition worsen or does not improve.

DO NOT USE THIS PRODUCT:

- If you are hypersensitive (allergic) to any of the ingredients listed.
- Do not accept this package if seals are broken.

INTERACTIONS

Always tell your healthcare professional if you are taking any other medicine. It is possible that exposure of certain supplement ingredients may interfere with certain medications. (See **Warnings & Special precautions**)

DOSAGE AND DIRECTIONS FOR USE

Adult: Take two (2) softgel capsules up to two times daily or as directed by your healthcare professional.

Do not take more than the recommended dose.

SIDE EFFECTS

Should your general health worsen, or if you experience any untoward effects while being exposed to this product, please consult your doctor, pharmacist or other healthcare professional for advice.

KNOWN SYMPTOMS OF OVER DOSAGE AND PARTICULARS OF ITS TREATMENT

See side-effects.

Treatment: Discontinue use and consult your doctor, pharmacist or other healthcare professional for advice.

IDENTIFICATION

Clear oblong vegetable softgel/golden fill.

PRESENTATION

A white 175 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

STORAGE INSTRUCTION

Store in a cool, dark place, below 25 °C.

Protect from direct sunlight and heat.

Store in the original bottle.

Keep the bottle tightly closed.

Replace the protective cap after each use.

Do not use after the expiry date stated on the bottle.

Do not use **OMGEAGENICS® ALGAE OMEGA-3S** if you notice visible signs of deterioration.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

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

NAME AND BUSINESS ADDRESS OF APPLICANT

Distributed by:

Amipro Advanced Development Products (Pty) Ltd
Unit 3, Eastgate Business Park, 1 South Road, Eastgate Extension,
Sandton, 2146, Tel: 011-802-8101

DATE OF PUBLICATION

To be allocated by the regulatory authority.

PROFESSIONELE INLIGTING

SKEDULERINGSSTATUS: S0

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.6 Vette, Olies en Vetsure

HANDELSNAAM EN DOSEERVORM,

OMGEAGENICS® ALGAE OMEGA-3S 300 mg,

60 Softgel Kapsules

SAMESTELING

Elke twee (2) softgel kapsules OMGEAGENICS® ALGAE OMEGA-3S bevat die volgende

aktiewe stowwe:

Omega-3-vetsure Trigliseriese (van mikroalge Schizochytrium sp.) (dele: heel)	600 mg
DHA (Dokosaheksaensuur trigliseriese)	360 mg
EPA (Eicosapentaensuur trigliseriese)	180 mg

Onaktiewe bestanddele: Algeolie, askorbilpalmitaat (antioksidant), natuurlike geur, softgel-dop [beta-karoteen (kleur), karamel (kleur), karrageen, gliserien, gemodifiseerde mielietystel, sorbitol, water.], sonneblomolie, gemengde tokoferole (antioksidant) en sonneblomesliten.

Bevat suiker: Sorbitol 76 mg

Hierdie produk is geskik vir vegetariërs, suiwel- en glutenvry en nie-GGO.

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

OMGEAGENICS® ALGAE OMEGA-3S help om kognitiewe gesondheid en breinfunksie te ondersteun. Beskik oor 'n gekonsentreerde, gesuiwerde vegetariese bron van omega-3-vetsure uit die mikroalge Schizochytrium sp. Elke softgel verskaf 300 mg omega-3 in die trigliseriesedvorm.

Bestanddele	Gebruik vir bestanddeel
Omega-3-vetsure trigliseriese	Kan help om trigliseriese in die bloed te verminder, wat die risiko van kardiovaskulêre siektes kan verlaag. Hulle is ook bekend vir hul anti-inflammatoriese eienskappe.
EPA (Eicosapentaensuur)	Om meer EPA in jou dieet te kry, het positiewe uitwerking op koronêre hartsiektes, hoë trigliseriese (vette in die bloed), hoë bloeddruk en inflammasie
DHA (Dokosaheksaensuur)	Lae vlakke word geassosieer met 'n verhoogde risiko van hartsiektes, en sommige studies toon dat aanvullings jou risiko verminder.

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie OMGEAGENICS® ALGAE OMEGA-3S neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. Moenie hierdie medisyne neem as jy 'n vis- of seekoosallergie het nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan voordat jy hierdie medisyne neem.

INTERAKSIES

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik. Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne kan interefer. (Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

As jy enige van die volgende gediagnoseerde toestande het, raadpleeg jou gesondheidsorgpraktisyn voor gebruik: Bipolêre versteuring, lewersiekte, diabetes, aritmie, ingeplante defibrillator. As jy die volgende medisyne neem, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy neem: Hoë bloeddruk medisyne, Geboortebepoeringspille, antikoagulanste (Warfarin). As enige van die volgende gebeur, hou op om OMGEAGENICS® ALGAE OMEGA-3S te gebruik en vertel jou dokter of gaan na die ongevale-afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, jek/swellings (veral van die gesig/tong/keel), erge duiseligheid, probleme met asemhaling;

Dit is alles baie ernstige gevolge. As jy dit het, het jy dalk 'n ernstige reaksie op OMGEAGENICS® ALGAE OMEGA-3S gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig he.

Neuwe-effekte wat gewoonlik nie mediese hulp benodig nie (rapporteer aan jou gesondheidsorgpraktisyn as hulle voortduur):

- Maagongemak, diarree, hardlywigheid, slapeloosheid

Dit is alles baie ernstige gevolge. As u dit het, het u moontlik 'n ernstige reaksie op OMGEAGENICS® ALGAE OMEGA-3S gehad. Miskien het u dringende mediese hulp of hospitalisasie nodig.

Raadpleeg 'n gesondheidsorgpraktisyn as u enige mediese toestand het. Staak gebruik onmiddellik indien enige nadelige reaksie plaasvind. Lees hierdie voulijet aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskif.

- Hou hierdie voulijet. Miskien moet u dit weer lees.

- Moenie medisyne met enige ander persoon deel nie.

- Vra jou apteker of jy meer inligting of advies benodig.

- Jy moet 'n dokter raadpleeg indien jou toestand vererger of nie verbeter nie.

MOENIE HIERDIE PRODUK GEBRUIK NIE:

- As jy hipersensitief (allergies) is vir enige van die bestanddele wat gelys word.

- Jy moet nie hierdie produk aanvaar as seëls gebreek word nie.

INTERAKSIES

Vertel altyd jou gesondheidsorgpraktisyn as jy enige ander medisyne gebruik Dit is moontlik dat blootstelling van sekere aanvullingsbestanddele met sekere medisyne 'n interaksie mag hê. (Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

DOSES EN AANWYSINGS VIR GEBRUIK

Volwasse: Neem twee (2) softgelkapsules tot twee keer per dag of soos voorgeskryf deur jou gesondheidsorgpraktisyn. **Moenie meer as die aanbevole dosis neem nie.**

NEWE-EFFEKTE

Indien jou algemene gesondheid vererger, of as jy enige nadelige effekte ervaar terwyl jy aan hierdie produk blootgestel word, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad.

BEKENDE SIMPTOME VAN OORDOERING EN BESONDERHEDE VAN DIE BEHANDELING

DAARVAN Sien neuwe-effekte.

Behandeling: Staak gebruik en raadpleeg jou dokter, apteker of ander gesondheidsorgpraktisyn vir advies.

IDENTIFIKASIE

Duidelike langwerpige groente softgel/goue vulsel.

AANBIEDING

'n Wit 175 ml HDPE-bottel met 'n wit dop, induksieseel, peuterkrimpseël, wattering en sliikagelsakkie.

BERGING INSTRUKSIE

Bêre in 'n koel, donker plek, onder 25 °C.

Beskermt teen direkte sonlig en hitte.

Bêre in die oorspronklike bottel. Hou die bottel styf toe.

Vervang die beskermdede dop na elke gebruik.

Moet nie gebruik word na die vervaldatum wat op die bottel aangedui word nie.

Moenie OMGEAGENICS® ALGAE OMEGA-3S gebruik as u sigbare tekens van agteruitgang opmerk nie.

Verkoel in die yskas na oopmaak en gebruik binne 90 dae. Hierdie olie kan troebel word wanneer dit verkoel word, wat normaal is en nie die doeltreffendheid van die produk verander nie.

REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeken te word.

Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

NAAM EN BESIGHEIDSADRES VAN AANSOEKER

Versprei deur:

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