

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® FISH OIL EPA-DHA 1000 mg,

60 soft gel Capsules

COMPOSITION

Each one (1) capsule of OMGEAGENICS® FISH OIL EPA-DHA contains the following

actives:

Marine Lipid Concentrate [fish oil (anchovy, sardine and mackerel)]	1,4 g
EPA (Eicosapentaenoic acid)	710 mg
DHA (Docosahexaenoic acid)	290 mg
Other Omega-3 Fatty Acids Triglycerides	100 mg

Inactive Ingredients: Ascorbyl palmitate, gelatine, glycerine, lemon flavour, mixed tocopherols, rosemary extract, water. **Contains: Fish** (anchovy, sardine, and mackerel).

This product is gluten free (Sugar Free)

PHARMACOLOGICAL CLASSIFICATION - Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

OMGEAGENICS® FISH OIL EPA-DHA features a concentrated and purified source of omega-3 fatty acids from sustainably sourced, coldwater fish to support cardiovascular health and helps to reduce the pain of rheumatoid arthritis, in conjunction with conventional therapy.

Ingredients	Uses for ingredient
Marine Lipid Concentrate	Multiple risk factors for heart disease appear to be reduced by consuming fish or fish oil. The benefits of fish oil for heart health, lower cholesterol, lower triglycerides, reduce blood pressure, prevent the formation of plaques that harden arteries ¹
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 ²
DHA (Docosahexaenoic acid)	Low levels are associated with an increased risk of heart disease, and some studies show that supplements reduce your risk. ³

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take OMGEAGENICS® FISH OIL EPA-DHA 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® FISH OIL EPA-DHA 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® FISH OIL EPA-DHA. 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® FISH OIL EPA-DHA. 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 one (1) capsule, three (3) times a day, with food 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

Lemon flavoured, softgel capsules.

PRESENTATION

A white 250 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® FISH OIL EPA-DHA 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.



Document Reference: OMG1000.PI.V01.CMP 10-24

¹ Effect of omega-3 fatty acids on cardiovascular outcomes: A systematic review and meta-analysis Khan, Safi U. et al. eClinicalMedicine, Volume 38, 100997

² Angerer P, von Schacky C. n-3 polyunsaturated fatty acids and the cardiovascular system. Curr Opin Lipidol. 2000;11(1):57-63.

³ Hara M, Sakata Y, Nakatani D, Suna S, Usami M, Matsumoto S, Hamasaki T, Doi Y, Nishino M, Sato H, Kitamura T, Nanto S, Hori M, Kumuro I. Osaka Acute Coronary Insufficiency Study (OACIS) Investigators. Low levels of serum n-3 polyunsaturated fatty acids are associated with worse heart failure-free survival in patients after acute myocardial infarction. Circ J. 2013;77(11):1533-62. doi: 10.1253/circj.12-0875. Epub 2012 Oct 6. PMID: 23047296.

PROFESSIONELE INLIGTING

SKEDULERINGSSTATUS^[50]

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.6 Vette, Olies en Vetsure

HANDELSNAAM EN DOSEERVORM,

OMGEAGENICS® FISH OIL EPA-DHA 1000 mg,

60 sagte gel kapsules

SAMESTELING

Elke (1) kapsule OMGEAGENICS® FISH OIL EPA-DHA bevat die volgende aktiewe stowwe:

Mariene lipied konsentraat	1,4 g
[visolie (ansjovis, sardien en makriel)]	
EPA (Eicosapentaensuur)	710 mg
DHA (Dokosaheksaensuur)	290 mg
Ander Omega-3-vetsure	100 mg

Onktoem bestanddele: Askorbylpalmitaat, gelatien, gliserien, suurlemoenguur, gemengde tokoferole, roommarynekstrak, water. **Bevat: Vis** (ansjovis, sardien en makriel).

Hierdie produk is glutenvry (suikervry)

FARMAKOLOGIESE KLASSEKASIE – Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

OMGEAGENICS® FISH OIL EPA-DHA beskik oor 'n gekonsentreerde en gesuiwerde bron van omega-3-vetsure van volhoubare kouewatervis om kardiovaskulêre gesondheid te ondersteun en help om die pijn vanumatoidie artritis te verminder, in samewerking met konvensionele terapie.

WAARSKUWING EN SPESIALE VOORSORGMATREËLS

As jy enige van die volgende gedagnoseerde 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, Geboortebeperkingspille, antikoagulant (Warfarin). As enige van die volgende gebeur, hou op om **OMGEAGENICS® FISH OIL EPA-DHA** te gebruik en vertel jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:

- Allergiese reaksies- uitslag, jeuk/swelling (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® FISH OIL EPA-DHA** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

Nowe-efekte 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® FISH OIL EPA-DHA** 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 voubijlet aandagtig deur, want dit bevat belangrike inligting vir u. Hierdie produk is beskikbaar sonder doktersvoorskrif.

- Hou hierdie voubijlet. 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 kan int erfere. (Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

DOSIS EN AANWYSINGS VIR GEBRUIK

Volwasse: Neem een (1) kapsule, drie (3) keer per dag, saam met kos 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 OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN

Sien newe-efekte.

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

IDENTIFIKASIE

Suurlemoengegeurde, softgel kapsules.

AANBIEDING

'n Wit 250 ml HDPE-bottel met 'n wit dop, induksiesêel, peuterkrimpseël, spons en slikgelsakkie.

BERGING INSTRUKSIE

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

Beskerm teen direkte sonlig en hitte.

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

Vervang die beskermende dop na elke gebruik.

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

Moenie **OMGEAGENICS® FISH OIL EPA-DHA** gebruik as u sigbare tekens van agteruitgang opmerk nie.

REGISTRASIE NOMMER

Om by registrasie deur SAHPRA toegeen te word. Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

NAAM EN BESIGHEIDSDRES VAN AANSOEKER

Versprei deur:

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



Bestanddele	Gebruik vir bestanddeel
Mariene lipied konsentraat	Veevuldige risikofaktore vir hartsiektes blyk verminder te word deur vis of visolie te verbruik. Die voordele van visolie vir hartgesondheid, laer cholesterol, laer trigliseriede, verlaag bloeddruk, voorkom die vorming van plate wat are verhard ⁴
EPA (Eicosapentaensuur)	Om meer EPA in jou dieet te kry, het positiewe uitwerking op koronêre hartsiektes, hoë trigliseriede (vette in die bloed), hoë bloeddruk en inflammasie ⁵
DHA (Dokosaheksaensuur)	Lae vlakke word geassosieer met 'n verhoogde risiko van hartsiektes, en sommige studies toon dat aanvullings jou risiko verminder. ⁶

KONTRA-INDIKASIES:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **OMGEAGENICS® FISH OIL EPA-DHA** neem as jy hipersensitief (allergies) is vir enige van die bestanddele nie. Moenie hierdie medisyne neem as jy 'n vis- of seekosallergie 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 int erfere. (Sien **Waarskuwings en Spesiale voorsorgmaatreëls**)

⁴ Effek van omega-3-vetsure op kardiovaskulêre uitkomst: 'n Sistematiese oorsig en meta-analise Khan, Safi U. et al. eClinicalMedicine, Deel 38, 100997

⁵ Angerer P, von Schacky C. n-3 poli-onversadigde vetsure en die kardiovaskulêre stelsel. Huidige Opin Lipidol. 2000; 11(1):57-63.

⁶ Hara M, Sakata Y, Nakatani D, Suna S, Usami M, Matsumoto S, Hamasaki T, Doi Y, Nishino M, Sato H, Kitamura T, Nanto S, Hori M, Kumuro I, Osaka Akute Koronêre Ontoerleikendstudie (OACS) Ondersoekers. Lae vlakke van serum n-3 poli-onversadigde vetsure word geassosieer met slegter hartversakingvrye oorlewing by pasiënte na akute miokardiale infarkte. Circ J. 2013; 77(1):153-62. doi: 10.1253/circj.12-0875. EPUB 2012 6 Okt. PMID: 23047296.

