

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® MEGA 10 300 mg,

60 Softgel Capsules

COMPOSITION

Each one (1) softgel capsules of OMGEAGENICS® MEGA 10 contains the following actives:

Marine Lipid Concentrate (fish oil)	782 mg
EPA (Eicosapentaenoic acid)	330 mg
DHA (Docosahexaenoic acid)	170 mg
Other Omega-3 Fatty Acids	60 mg
Omega-7 Oil (as <i>hippophae rhamnoides</i>) [fruit]	210 mg
Palmitoleic Acid	110 mg

Inactive Ingredients: Contains 2 percent or less of natural lemon flavour and mixed tocopherols (antioxidant), fish oil (anchovy, sardine), softgel shell (gelatin, glycerin, water, pectin).

Contains Sugar: Sorbitol (30,6 mg)

This product is dairy & gluten free and non-GMO.

PHARMACOLOGICAL CLASSIFICATION

Complementary Medicine

INDICATION & PHARMACOLOGICAL ACTION

OMGEAGENICS® MEGA 10 features a combination of omega-3 and omega-7 fatty acids to help support healthy triglyceride levels already within the normal range. This formula supports immune function and cardiovascular health.

Ingredients	Uses for ingredient
Omega-3 Fatty Acids	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.
Omega-7 Oil	Omega-7 helps with the process of burning fat and sugar molecules.
Palmitoleic Acid	Benefits include improving skin health, regulating metabolism, and reducing inflammation.

CONTRA INDICATIONS:

If you are taking any chronic medication, do not use this product without consulting your healthcare professional. Do not take **OMGEAGENICS® MEGA 10** 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

Patients with the rare hereditary condition of sorbitol intolerance should not take **OMGEAGENICS® MEGA 10**. Contains sorbitol which may have a laxative effect and may have an effect on the glycaemic control of patients with diabetes mellitus. 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® MEGA 10** 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® MEGA 10**. 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® MEGA 10**. 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, 1 to 2 times daily 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

Clear oblong gelatine 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® MEGA 10** 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® MEGA 10 300 mg,

60 Softgel Kapsule

SAMESTELING

Elke een (1) softgel kapsule OMGEAGENICS® MEGA 10 bevat die volgende aktiewe stowwe:

Mariene lipiedkontraat (visolie)	782 mg
EPA (Eicosapentaensuur)	330 mg
DHA (Dokosaheksaensuur)	170 mg
Ander Omega-3-vetsure	60 mg
Omega-7 Olie (as <i>seekoek rhamnoides</i>) [vrugte]	210 mg
Palmitoleiensuur	110 mg

Onaktiewe bestanddele: Bevat 2 persent of minder natuurlike suurlemoengeur en gemengde tokoferole (antioksidant), visolie (ansjovis, sardien), softgel-dop (gelatien, gliserien, water, pektien).

Bevat suiker: Sorbitol (30,6 mg)

Hierdie produk is suiwel- en glutenvry en nie-GMO.

FARMAKOLOGIESE KLASSIFIKASIE

Komplementêre medisyne

AANDUIDING EN FARMAKOLOGIESE WERKING

OMGEAGENICS® MEGA 10 beskik oor 'n kombinasie van omega-3 en omega-7-vetsure om gesonde trigliseriedvlakke wat reeds binne die normale omvang is, te ondersteun. Hierdie formule ondersteun immuunfunksie en kardiovaskulêre gesondheid.

Bestanddele	Gebruik vir bestanddeel
Omega-3-vetsure	Kan help om trigliseriede 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 trigliseriede (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.
Omega-7 olie	Omega-7 help met die proses om vet- en suikermolekules te verbrand.
Palmitoleiensuur	Voordele sluit in die verbetering van velgesondheid, die regulering van metabolisme en die vermindering van inflammasie.

KONTRA-INDIKASIE:

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **OMGEAGENICS® MEGA 10** 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.

INTERAKSIE

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

WAARSKUWING EN SPESIALE VOORSORGMAATREËLS

Pasiënte met die seldsame oorerflikke toestand van sorbitol-onverdraagsaamheid moet nie **OMGEAGENICS® MEGA 10** neem nie. Bevat sorbitol wat 'n lakseermiddel kan hê en 'n effek kan hê op die glukemiese beheer van pasiënte met diabetes mellitus. 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, Geboortebepelingspille, antikoagulanter (Warfarin). As enige van die volgende gebeur, hou op om **OMGEAGENICS® MEGA 10** 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® MEGA 10** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

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® MEGA 10** 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 doktersvoorskrif.

- 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.

INTERAKSIE

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

DOSES EN AANWYSINGS VIR GEBRUIK

Volwasse: Neem een (1) kapsule, 1 tot 2 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 OORDOOSERING 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 gelatien softgel/goue vulsel.

AANBIEDING

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

BERGING INSTRUKSIE

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

Beskermer teen direkte sonlig en hitte.

Bêre 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® MEGA 10 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 NUMMER

Om by registrasie deur SAHPRA toegeken 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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Sandton, 2146,
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