

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

Category D: Complementary medicine.

Discipline: Health Supplement

34.6 Fats, Oils and Fatty Acids

PROPRIETARY NAME, STRENGTH, PHARMACEUTICAL FORM -

OMGEAGENICS® ALGAE OMEGA-3s 300 mg, 60 Softgel Capsules

READ ALL OF THIS LEAFLET CAREFULLY BECAUSE IT CONTAINS
IMPORTANT INFORMATION FOR YOU

- **OMGEAGENICS® ALGAE OMEGA-3S** is available without a doctor's prescription.
- Nevertheless, you still need to use **OMGEAGENICS® ALGAE OMEGA-3S** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **OMGEAGENICS® ALGAE OMEGA-3S** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

WHAT IS IN THIS LEAFLET

- What **OMGEAGENICS® ALGAE OMEGA-3S** is and what it is used for.
- What you need to know before you take **OMGEAGENICS® ALGAE OMEGA-3S**.
- How to take **OMGEAGENICS® ALGAE OMEGA-3S**.
- Possible side effects.
- How to store **OMGEAGENICS® ALGAE OMEGA-3S**.
- Contents of the pack and other information.

WHAT OMGEAGENICS® ALGAE OMEGA-3S CONTAINS

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.

WHAT OMGEAGENICS® ALGAE OMEGA-3S IS AND WHAT IT IS USED FOR
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.

BEFORE YOU TAKE OMGEAGENICS® ALGAE OMEGA-3S

If you are taking any chronic medication, do not use this product without consulting your healthcare practitioner. 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.

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

PREGNANCY AND BREASTFEEDING

Safety during pregnancy and breastfeeding has not been established, consult with your healthcare professional before use. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult with your healthcare professional before taking this supplement.

DRIVING AND USING MACHINES

It is not always possible to predict to what extent **OMGEAGENICS® ALGAE OMEGA-3S** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in activities relating to requiring mental alertness, judgement and/or sound co-ordination and vision e.g. driving, riding, flying, sailing, operating machines/equipment, until they are aware of the measure to which **OMGEAGENICS® ALGAE OMEGA-3S** may affect you.

TAKING OTHER MEDICINES WITH OMGEAGENICS® ALGAE OMEGA-3S

Complementary medicine products contain ingredients which may interact with some medication. If you are taking any chronic medication, do not use this product without consulting your healthcare practitioner.

HOW TO TAKE OMGEAGENICS® ALGAE OMEGA-3S

Do not share medicines prescribed for you with any other person. Always take **OMGEAGENICS® ALGAE OMEGA-3S** exactly as described in this leaflet, or as your doctor, healthcare professional has instructed you. You should check with your doctor, pharmacist or healthcare professional if you are unsure.

Directions for use:

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

Do not take more than the recommended dose.

IF YOU TAKE MORE OMGEAGENICS® ALGAE OMEGA-3S THAN YOU SHOULD

In the event of overdose, consult your doctor, pharmacist. Should none of these be available, contact the nearest hospital or poison control centre.

IMPORTANT INFORMATION ABOUT SOME OF THE INGREDIENTS OF OMGEAGENICS® ALGAE OMEGA-3S

Contains sorbitol which may have a laxative effect. **OMGEAGENICS® ALGAE OMEGA-3S** contains sorbitol. If you have been told that you have an intolerance to some sugars, you should not take **OMGEAGENICS® ALGAE OMEGA-3S**.



IF YOU FORGET TO TAKE OMGEAGENICS® ALGAE OMEGA-3S

Do not take a double dose to make up for a missed dose.

POSSIBLE SIDE EFFECTS

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

Not all side effects and interactions reported for **OMGEAGENICS® ALGAE OMEGA-3S** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor, pharmacist or healthcare practitioner.

REPORTING OF SIDE EFFECTS

If you experience side effects, talk to your doctor, pharmacist or other healthcare practitioner. You can also report side effects to SAHPRA via "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **OMGEAGENICS® ALGAE OMEGA-3S**.

STORAGE AND DISPOSING OF OMGEAGENICS® ALGAE OMEGA-3S

Store all medicines out of the reach of children.

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

Protect from direct sunlight and heat.

Store in the original packaging.

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.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF OMGEAGENICS® ALGAE OMEGA-3S

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

IDENTIFICATION OF OMGEAGENICS® ALGAE OMEGA-3S

Clear oblong vegetable softgel/golden fill.

REGISTRATION NUMBER

To be allocated by SAHPRA upon registration.

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

THIS LEAFLET WAS LAST REVISED ON

10 January 2025

NAME AND ADDRESS OF REGISTRATION HOLDER

Distributed by:

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Sandton, 2146
Tel: 011-802-8101



PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.
Disipliene: Gesondheidsaanvulling
34.6 Vette, Olies en Vetsure

HANDELSNAAM EN DOSEERVORM,

OMGEAGENICS® ALGAE OMEGA-3S 300 mg,

60 Softgel Kapsules

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT BELANGRIKE INLIGTING VIR U

- **OMGEAGENICS® ALGAE OMEGA-3S** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **OMGEAGENICS® ALGAE OMEGA-3S** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **OMGEAGENICS® ALGAE OMEGA-3S** met enige ander persoon deel nie.
- Vra jou apteker of gesondheidsorgpraktisyn of jy meer inligting of advies benodig.

WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **OMGEAGENICS® ALGAE OMEGA-3S** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **OMGEAGENICS® ALGAE OMEGA-3S** neem.
- Hoe om **OMGEAGENICS® ALGAE OMEGA-3S** te neem.
- Moontlike nuwe-effekte.
- Hoe om **OMGEAGENICS® ALGAE OMEGA-3S** op te bêre.
- Inhoud van die pak en ander inligting

WAT OMGEAGENICS® ALGAE OMEGA-3S BEVAT

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

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

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

Bevat suiker: Sorbitol 76 mg

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

WAT IS OMGEAGENICS® ALGAE OMEGA-3S VLOEISTOF EN WAARVOOR WORD DIT GEBRUIK

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

VOORDAT JY OMGEAGENICS® ALGAE OMEGA-3S NEEM

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 sekoosallergie het nie. As jy allergieë het, maak seker dat jy met jou gesondheidsorgpraktisyn gaan praat voordat jy hierdie aanvulling neem. Hierdie medisyne is nie deur SAHPRA geëvalueer vir kwaliteit, veiligheid of beoogde gebruik nie.

SWANGERSKAP EN BORSVOEDING

Veiligheid tydens swangerskap en borsvoeding is nie vasgestel nie, raadpleeg u gesondheidsorgpraktisyn voor gebruik. As jy swanger is of borsvoed, dink jy kan swanger wees of beplan om 'n baba te hê, raadpleeg asseblief jou gesondheidsorgpraktisyn voordat jy hierdie aanvulling neem.

BESTUUR EN GEBRUIK VAN MASHIENE

Dit is nie altyd moontlik om te voorspel in watter mate **OMGEAGENICS® ALGAE OMEGA-3S** die daaglikse aktiwiteite van 'n pasiënt kan belemmer nie. Pasiënte moet seker maak dat hulle nie betrokke raak by aktiwiteite wat verband hou met die vereiste van verstandelike waaksaamheid, oordeel en/of gesonde koördinasie en visie nie, byvoorbeeld bestuur, ry, vlieg, seil, bedryfsmasjien/toerusting, totdat hulle bewus is van die mate waartoe **OMGEAGENICS® ALGAE OMEGA-3S** jou beïnvloed.

NEEM ANDER MEDISYNE MET OMGEAGENICS® ALGAE OMEGA-3S

Komplementêre medisyne produkte bevat bestanddele wat met sommige medisyne kan wissel. As jy enige chroniese medisyne gebruik, moenie hierdie produk gebruik sonder om jou mediese praktisyn te raadpleeg nie.

HOE OM OMGEAGENICS® ALGAE OMEGA-3S TE NEEM

Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Neem altyd **OMGEAGENICS® ALGAE OMEGA-3S** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, of gesondheidsorgpraktisyn voorgeskryf het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

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.

AS JY MEER OMGEAGENICS® ALGAE OMEGA-3S NEEM AS WAT JY MOET

In die geval van oordosering, raadpleeg u dokter, apteker. Indien nie een hiervan beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

AS JY VERGEET OM OMGEAGENICS® ALGAE OMEGA-3S TE NEEM

Moenie 'n dubbele dosis neem om op te maak vir 'n dosis wat oorgeslaan is nie

MOONTLIKE NUWE-EFFEKTE

OMGEAGENICS® ALGAE OMEGA-3S kan nuwe-effekte hê.

As jy enige van die volgende gedignoseerde 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, Geboortebepoerkingsspile, antikoagulant (Warfarin). As enige van die volgende gebruik, hou op om **OMGEAGENICS® ALGAE OMEGA-3S** 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® ALGAE OMEGA-3S** gehad. Jy sal dalk dringende mediese hulp of hospitalisasie nodig hê.

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

- Maagongemak, diarree.

Nie alle nuwe-effekte en interaksies wat vir **OMGEAGENICS® ALGAE**

OMEGA-3S rapporteer word, is by hierdie inligtingsblad ingesluit nie.

Indien jou algemene gesondheid vererger of as jy enige nadelige effekte ervaar tydens die gebruik van hierdie medisyne, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgpraktisyn vir raad. As jy enige nuwe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

AANMELDING VAN NUWE-EFFEKTE

As jy nuwe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook nuwe-effekte aan SAHPRA rapporteer via "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies:

<https://www.sahpra.org.za/Publications/Index/8>. Deur nuwe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van

OMGEAGENICS® ALGAE OMEGA-3S.

HOE OM OMGEAGENICS® ALGAE OMEGA-3S TE BÊRE

Bêre alle medisyne buite bereik van kinders.

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

Beskermt teen direkte sonlig en hitte.

Bêre nie die oorspronklike verpakking.

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.

Moenie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

AANBIEDING VAN OMGEAGENICS® ALGAE OMEGA-3S

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

IDENTIFIKASIE VAN OMGEAGENICS® ALGAE OMEGA-3S

Duidelike langwerpige groente softgel/goue vulsel.

REGISTRASIONOMMER

Om deur SAHPRA toegeken te word by registrasie.

TOEGANG TOT DIE OOREENSTEMMende PROFESSIONELE INLIGTING

Skandeer QR-kode.

HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

10 Januarie 2025

NAAM EN ADRES VAN REGISTRASIEHOUER

Versprei deur:

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