

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 -

OMEGAGENICS® FISH OIL EPA-DHA 1000 mg, 60 softgel capsules

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

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

WHAT IS IN THIS LEAFLET

- What OMEGAGENICS® FISH OIL EPA-DHA is and what it is used for.
- What you need to know before you take OMEGAGENICS® FISH OIL EPA-DHA.
- How to take OMEGAGENICS® FISH OIL EPA-DHA.
- Possible side effects.
- How to store OMEGAGENICS® FISH OIL EPA-DHA.
- Contents of the pack and other information.

WHAT OMEGAGENICS® FISH OIL EPA-DHA CONTAINS

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

Marine Lipid Concentrate [fish oil]	1,4 g
EPA (Eicosapentaenoic acid)	710 mg
DHA (Docosahexaenoic acid)	290 mg

Inactive ingredients: Ascorbyl palmitate, gelatine, glycerine, lemon flavour, mixed tocopherols, rosemary extract, water.

This product is gluten free (Sugar Free)

WHAT OMEGAGENICS® FISH OIL EPA-DHA IS AND WHAT IT IS USED FOR

OMEGAGENICS® 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.

BEFORE YOU TAKE OMEGAGENICS® FISH OIL EPA-DHA

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

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 OMEGAGENICS® FISH OIL EPA-DHA 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 OMEGAGENICS® FISH OIL EPA-DHA may affect you.

TAKING OTHER MEDICINES WITH OMEGAGENICS® FISH OIL EPA-DHA

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 OMEGAGENICS® FISH OIL EPA-DHA

Do not share medicines prescribed for you with any other person. Always take OMEGAGENICS® FISH OIL EPA-DHA 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 one (1) capsule, three (3) times daily with food or as directed by your healthcare practitioner

Do not take more than the recommended dose.

IF YOU TAKE MORE OMEGAGENICS® FISH OIL EPA-DHA 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.



IF YOU FORGET TO TAKE OMEGAGENICS® FISH OIL EPA-DHA

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, oral contraceptive medicine, anticoagulants (Warfarin).

If any of the following happens, stop using OMEGAGENICS® 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 OMEGAGENICS® 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

Not all side effects and interactions reported for OMEGAGENICS® FISH OIL EPA-DHA 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 OMEGAGENICS® FISH OIL EPA-DHA.

STORAGE AND DISPOSING OF OMEGAGENICS® FISH OIL EPA-DHA

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 OMEGAGENICS® FISH OIL EPA-DHA if you notice visible signs of deterioration.

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

PRESENTATION OF OMEGAGENICS® FISH OIL EPA-DHA

A white 250 ml HDPE bottle with a white cap, induction seal, tamper shrink seal, wadding and silica gel sachet.

IDENTIFICATION OF OMEGAGENICS® FISH OIL EPA-DHA

Lemon flavoured, softgel capsules

REGISTRATION NUMBER - To be allocated by SAHPRA upon registration.

ACCESS TO THE CORRESPONDING PROFESSIONAL INFORMATION

Scan QR code.

THIS LEAFLET WAS LAST REVISED ON

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NAME AND ADDRESS OF REGISTRATION HOLDER

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PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

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

HANDELSNAAM EN DOSEERVORM,

OMEGAGENICS® FISH OIL EPA-DHA 1000 mg,

60 Sagtegel Kapsules

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

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

WAT IS IN HIERDIE INLIGTINGSBLAD

- Wat **OMEGAGENICS® FISH OIL EPA-DHA** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **OMEGAGENICS® FISH OIL EPA-DHA** neem.
- Hoe om **OMEGAGENICS® FISH OIL EPA-DHA** te neem.
- Moontlike nuwe-effekte.
- Hoe om **OMEGAGENICS® FISH OIL EPA-DHA** te bêre.
- Inhoud van die pak en ander inligting.

WAT OMEGAGENICS® FISH OIL EPA-DHA BEVAT

Elke een (1) kapsule **OMEGAGENICS® FISH OIL EPA-DHA** bevat die volgende aktiewe:

Mariene lipied konsentraat [visolie]	1,4 g
EPA (Eikosapentaensuur)	710 mg
DHA (Dokosahexaensuur)	290 mg

Onaktiewe bestanddele: Askorbielpalmataat, gelatien, gliserien, suurlemoen geur, gemengde tokoferole, roosmaryn ekstrak, water.

Hierdie produk is **glutenvry (suikervry)**

WAT IS OMEGAGENICS® FISH OIL EPA-DHA EN WAARVOOR WORD DIT GEBUIK

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

VOORDAT JY OMEGAGENICS® FISH OIL EPA-DHA NEEM

As jy enige chroniese medisyne neem, moenie hierdie produk gebruik sonder om jou gesondheidsorgpraktisyn te raadpleeg nie. Moenie **OMEGAGENICS® 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 seeksalergieë 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 GEBUIK VAN MASHIENE

Dit is nie altyd moontlik om te voorspel in watter mate **OMEGAGENICS® FISH OIL EPA-DHA** 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, bedryfsmasjiene/toerusting, totdat hulle bewus is van die mate waartoe **OMEGAGENICS® FISH OIL EPA-DHA** jou beïnvloed.

NEEM ANDER MEDISYNE MET OMEGAGENICS® FISH OIL EPA-DHA

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 OMEGAGENICS® FISH OIL EPA-DHA TE NEEM

Moenie medisyne wat vir u voorgeskrif is, met enige ander persoon deel nie. Neem altyd **OMEGAGENICS® FISH OIL EPA-DHA** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, of gesondheidsorgpraktisyn voorgeskrif het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

Aanwysings vir gebruik:

Volwasse: Neem een (1) kapsule drie (3) keer daaglik met etes, of soos voorgeskrif deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

AS JY MEER OMEGAGENICS® FISH OIL EPA-DHA 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 OMEGAGENICS® FISH OIL EPA-DHA TE NEEM

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

MOONTLIKE NUWE-EFFEKTE

OMEGAGENICS® FISH OIL EPA-DHA kan nuwe-effekte hê.

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, orale voorbehoedemiddele, antikoagulant (Warfarin). As enige van die volgende gebeur, hou op om **OMEGAGENICS® 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 **OMEGAGENICS® FISH OIL EPA-DHA** 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 **OMEGAGENICS® FISH OIL EPA-DHA** gerapporteer 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

OMEGAGENICS® FISH OIL EPA-DHA.

HOE OM OMEGAGENICS® FISH OIL EPA-DHA TE BÊRE

Bêre alle medisyne buite bereik van kinders.

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

Beskermer teen direkte sonlig en hitte.

Bêre in die oorspronklike verpakking.

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

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

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

AANBIEDING VAN OMEGAGENICS® FISH OIL EPA-DHA

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

IDENTIFIKASIE VAN OMEGAGENICS® FISH OIL EPA-DHA

Suurlemoengeurde, sagtegel kapsules.

REGISTRASIE NUMMER - Om deur SAHPRA toegeken te word by

registrasie.

TOEGANG TOT DIE OOREENSTEMMENDE PROFESSIONELE INLIGTING

Skandeer QR-kode.

HIERDIE INLIGTINGSBLAD IS LAAS HERSIEN OP

24 Oktober 2024

NAAM EN ADRES VAN REGISTRASIEHOUDER

Versprei deur:

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