

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® MEGA 10 300 mg,

60 Softgel Capsules

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

- **OMGEAGENICS® MEGA 10** is available without a doctor's prescription.
- Nevertheless, you still need to use **OMGEAGENICS® MEGA 10** carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share **OMGEAGENICS® MEGA 10** with any other person.
- Ask your pharmacist or healthcare professional if you need more information or advice.

WHAT IS IN THIS LEAFLET

- What **OMGEAGENICS® MEGA 10** is and what it is used for.
- What you need to know before you take **OMGEAGENICS® MEGA 10**.
- How to take **OMGEAGENICS® MEGA 10**.
- Possible side effects.
- How to store **OMGEAGENICS® MEGA 10**.
- Contents of the pack and other information.

WHAT OMGEAGENICS® MEGA 10CONTAINS

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.

WHAT OMGEAGENICS® MEGA 10 IS AND WHAT IT IS USED FOR

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.

BEFORE YOU TAKE OMGEAGENICS® MEGA 10

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

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® MEGA 10** 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® MEGA 10** may affect you.

TAKING OTHER MEDICINES WITH OMGEAGENICS® MEGA 10

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® MEGA 10

Do not share medicines prescribed for you with any other person. Always take **OMGEAGENICS® MEGA 10** 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, 1 to 2 times daily with food or as directed by your healthcare practitioner

Do not take more than the recommended dose.

IF YOU TAKE MORE OMGEAGENICS® MEGA 10 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® MEGA 10

Contains sorbitol which may have a laxative effect. **OMGEAGENICS® MEGA 10** contains sorbitol. If you have been told that you have an intolerance to some sugars, you should not take **OMGEAGENICS® MEGA 10**.



IF YOU FORGET TO TAKE OMGEAGENICS® MEGA 10

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® 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

Not all side effects and interactions reported for **OMGEAGENICS® MEGA 10** 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® MEGA 10**.

STORAGE AND DISPOSING OF OMGEAGENICS® MEGA 10

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® MEGA 10** if you notice visible signs of deterioration.

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

PRESENTATION OF OMGEAGENICS® MEGA 10

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

IDENTIFICATION OF OMGEAGENICS® MEGA 10

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
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PASIËNT INLIGTINGSBLAD

SKEDULERINGSSTATUS: **S0**

Kategorie D: Komplementêre medisyne.

Dissipline: Gesondheidsaanvulling

34.6 Vette, Olies en Vetsure

HANDELSNAAM EN DOSEERVORM,

OMGEAGENICS® MEGA 10 300 mg,

60 Softgel Kapsules

LEES HIERDIE INLIGTINGSBLAD NOUKEURIG, WANT DIT BEVAT

BELANGRIKE INLIGTING VIR U

- **OMGEAGENICS® MEGA 10** is beskikbaar sonder doktersvoorskrif.
- U moet steeds **OMGEAGENICS® MEGA 10** versigtig gebruik om die beste resultate daaruit te kry.
- Hou hierdie inligtingsblad. Miskien moet u dit weer lees.
- Moenie **OMGEAGENICS® MEGA 10** 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® MEGA 10** is en waarvoor dit gebruik word.
- Wat jy moet weet voordat jy **OMGEAGENICS® MEGA 10** neem.
- Hoe om **OMGEAGENICS® MEGA 10** te neem.
- Moontlike newe-effekte.
- Hoe om **OMGEAGENICS® MEGA 10** op te bêre.
- Inhoud van die pak en ander inligting

WAT OMGEAGENICS® MEGA 10 BEVAT

Eke een (1) softgel kapsules OMGEAGENICS® MEGA 10 bevat die volgende aktiewe:

Mariene lipiedkonsentraat (visolie)	782 mg
EPA (Eicosapentaensuur)	330 mg
DHA (Dokosaheksaensuur)	170 mg
Ander Omega-3-vetsure	60 mg
Omega-7 Olie (as seekoei <i>rhannoides</i>) [vrugte]	210 mg
Palmitoleïensuur	110 mg

Onaktiewe bestanddele: Bevat 2 persent of minder natuurlike suurlemoengneur 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-GGO.

WAT IS OMGEAGENICS® MEGA 10 VLOEISTOF EN WAARVOOR WORD DIT GEBRUIK

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 formulêre ondersteun immuunfunksie en kardiovaskulêre gesondheid.

VOORDAT JY OMGEAGENICS® MEGA 10 NEEM

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 seekoosallergie 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 MASIENE

Dit is nie altyd moontlik om te voorspel in watter mate **OMGEAGENICS® MEGA 10** 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, bedryfmasjiene/toerusting, totdat hulle bewus is van die mate waartoe **OMGEAGENICS® MEGA 10** jou beïnvloed.

NEEM ANDER MEDISYNE MET OMGEAGENICS® MEGA 10

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® MEGA 10 TE NEEM

Moenie medisyne wat vir u voorgeskrif is, met enige ander persoon deel nie. Neem altyd **OMGEAGENICS® MEGA 10** presies soos beskryf in hierdie inligtingsblad, of soos u dokter, of gesondheidsorgpraktisyn voorgeskrif het. Raadpleeg jou dokter, apteker of gesondheidsorgpraktisyn as jy onseker is.

BELANGRIKE INLIGTING OOR SOMMIGE VAN DIE BESTANDELE VAN OMGEAGENICS® MEGA 10

Bevat sorbitol wat 'n laxemiddel kan hê. **OMGEAGENICS® MEGA 10** bevat sorbitol. As jy meegedeel is dat jy 'n onverdraagsaamheid teenoor sommige suikers het, moet jy nie **OMGEAGENICS® MEGA 10** neem nie.

Aanwysings vir gebruik:

Volwasse: Neem een (1) kapsule, 1 tot 2 keer per dag saam met kos of soos voorgeskrif deur jou gesondheidsorgpraktisyn.

Moenie meer as die aanbevole dosis neem nie.

AS JY MEER OMGEAGENICS® MEGA 10 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® MEGA 10 TE NEEM

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

MOONTLIKE NEWE-EFFEKTE

OMGEAGENICS® MEGA 10 kan newe-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, Geboortebeperringsspilte, antikoagulerende (Warfarin). As enige van die volgende gebeur, hou op om **OMGEAGENICS® MEGA 10** te gebruik en vertel jou dokter of gaan na die ongevallende afdeling by jou naaste hospitaal:

- Allergiese reaksie-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.

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

- Maagongemak, diarree.

Nie alle newe-effekte en interaksies wat vir **OMGEAGENICS® MEGA 10** 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 newe-effekte sien wat nie in hierdie inligtingsblad genoem word nie, stel asseblief jou dokter, apteker of gesondheidsorgpraktisyn in kennis.

AANMELDING VAN NEWE-EFFEKTE

As jy newe-effekte ervaar, praat met jou dokter, apteker of ander gesondheidsorgpraktisyn. U kan ook newe-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 newe-effekte aan te meld, kan u help om meer inligting te verskaf oor die veiligheid van **OMGEAGENICS® MEGA 10**.

HOE OM OMGEAGENICS® MEGA 10 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 in die oorspronklike verpakking.

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.

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

AANBIEDING VAN OMGEAGENICS® MEGA 10

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

IDENTIFIKASIE VAN OMGEAGENICS® MEGA 10

Duidelike langwerpige gelatien 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 REGISTRASIEHOUDER

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