

PROFESSIONAL INFORMATION**D 34.6 Fats, Oils and Fatty Acids. Complementary Medicine: Health Supplement**

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

SCHEDULING STATUS: S0

1. NAME OF THE MEDICINE

LOCAL HEALTH OMEGA 3 softgel capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each softgel capsule contains:

| | |
|--------------------------------------|---------|
| Fish Oil | 1000 mg |
| Of which Eicosapentaenoic Acid (EPA) | 180 mg |
| Of which Docosahexaenoic Acid (DHA) | 120 mg |

Contains sugar: 40 mg glycerol per softgel capsule.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Yellow softgel capsules.

4. CLINICAL PARTICULARS**4.1 Therapeutic indications**

LOCAL HEALTH OMEGA 3 is a source of omega-3 fatty acids, EPA and DHA, for the support of cardiovascular health and brain function, and for the maintenance of good health.

4.2 Posology and method of administration

Adults and children 6 years and older: one to three (1-3) softgel capsules daily with a meal.

4.3 Contraindications

- Hypersensitivity to any of the active substances or to any of the excipients listed in section 6.1.
- Allergy to fish.

4.4 Special warnings and precautions for use

- Concomitant use of fish oil with anticoagulant or antiplatelet drugs may increase the risk of bleeding in patients taking anticoagulants or patients with a blood clotting disorder.

4.5 Interaction with other medicines and other forms of interaction

- High doses of fish oil might have antiplatelet effects. Concomitant use of fish oil with anticoagulant or antiplatelet drugs might increase the risk of bleeding.
- Some research suggests that fish oil increases antiplatelet effects when used with aspirin.
- Concomitant use of fish oil and dipyridamole may increase the risk of bleeding.
- Fish oils may modestly lower blood pressure and may have additive effects in patients taking both fish oil and antihypertensive drugs.

4.6 Fertility, pregnancy and lactation

Use in pregnancy should be supervised.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that LOCAL HEALTH OMEGA 3 does not adversely affect their performance.

4.8 Undesirable effects**Gastrointestinal**

Frequent: halitosis, fishy aftertaste and breath, heartburn, dyspepsia, nausea, loose stools, gastrointestinal upset.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

In the event of an overdose, undesirable effects as listed in 4.8 can be precipitated or be of increased severity.

Treatment of overdose is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES**5.1 Pharmacodynamic properties**

Omega-3 fatty acids, EPA and DHA, are required for the support of cardiovascular health and brain function, and for the maintenance of good health.

5.2 Pharmacokinetic properties

Eicosapentaenoic Acid (EPA) and **Docosahexaenoic Acid (DHA)**, in fish oil are well absorbed as ethyl esters or triglycerides. Available research shows that dietary intake of EPA and DHA increases levels of omega-3 fatty acids in serum, plasma, and leukocyte, monocyte, myocardial and erythrocyte phospholipids. DHA is abundant in neural and retinal tissue.

6. PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

Bovine gelatin, glycerol, purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

Store in the original package in order to protect from moisture.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

30/90 softgel capsules in a white, PET plastic container and white screwcap lid.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

CJ Distribution

23 Stag Road, Glen Austin, Johannesburg, South Africa

careline@cjdsa.com

011 589 2729

www.localhealth.com

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

**PATIENT INFORMATION LEAFLET
SCHEDULING STATUS**

LOCAL HEALTH OMEGA 3 (softgel capsules)

Each softgel capsule contains:

| | |
|--------------------------------------|---------|
| Fish Oil | 1000 mg |
| Of which Eicosapentaenoic Acid (EPA) | 180 mg |
| Of which Docosahexaenoic Acid (DHA) | 120 mg |

Contains sugar: 40 mg glycerol per softgel capsule.

Complementary Medicine: Fats, Oils and Fatty Acids (Health Supplement)

This unregistered medicine has not been evaluated by SAHPRA for its quality, safety or intended use. Health supplements are intended only to complement health or supplement the diet.

Read all of this leaflet carefully because it contains important information for you.

LOCAL HEALTH OMEGA 3 is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use LOCAL HEALTH OMEGA 3 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LOCAL HEALTH OMEGA 3 with any other person.
- Ask your healthcare practitioner or pharmacist if you need more information or advice.

What is in this leaflet

1. What LOCAL HEALTH OMEGA 3 is and what it is used for.
2. What you need to know before you use LOCAL HEALTH OMEGA 3.
3. How to use LOCAL HEALTH OMEGA 3.
4. Possible side effects.
5. How to store LOCAL HEALTH OMEGA 3.
6. Contents of the pack and other information.

1. What LOCAL HEALTH OMEGA 3 is and what it is used for

LOCAL HEALTH OMEGA 3 is a source of omega-3 fatty acids, EPA and DHA, for the support of cardiovascular health and brain function, and for the maintenance of good health.

2. What you need to know before you use LOCAL HEALTH OMEGA 3

Do not use LOCAL HEALTH OMEGA 3:

- If you are allergic or sensitive to any of the ingredients listed in section 6.
- If you are allergic to fish.

Warnings and precautions

Consult with a healthcare practitioner prior to using LOCAL HEALTH OMEGA 3, especially if you have a medical condition. Use LOCAL HEALTH OMEGA 3 with caution and consult a healthcare practitioner before use:

- If you suffer from a bleeding disorder or are taking blood-thinning medications.

Children and adolescents

LOCAL HEALTH OMEGA 3 is not recommended for children below the age of 6 years. Consult a healthcare practitioner prior to use.

Other medicines and LOCAL HEALTH OMEGA 3

Always tell your healthcare practitioner if you are taking any other medicine (this includes complementary or traditional medicines). Not all possible interactions with other medicines may be included in this leaflet. Consult with a healthcare practitioner prior to use. LOCAL HEALTH OMEGA 3 may interact with the following medications: anticoagulants, aspirin, dipyridamol, anti-hypertensive drugs.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare practitioner for advice before using LOCAL HEALTH OMEGA 3.

Driving and using machinery

No studies on the effects on the ability to drive or use of machinery have been performed. Patients should exercise caution before driving or using machinery until they are reasonably certain that LOCAL HEALTH OMEGA 3 does not adversely affect their performance.

3. How to use LOCAL HEALTH OMEGA 3

Do not share medicines prescribed to you with any other person. Do not exceed the daily recommended dosage. Always use LOCAL HEALTH OMEGA 3 exactly as described in this leaflet or as your healthcare practitioner has instructed. Check with your healthcare practitioner if you are not sure.

Adults and children 6 years and older:

Take one to three (1-3) softgel capsules daily with a meal, or as recommended by a healthcare practitioner.

4. Possible side effects

LOCAL HEALTH OMEGA 3 can have side effects. Not all side effects reported for LOCAL HEALTH OMEGA 3 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking LOCAL HEALTH OMEGA 3, please consult your doctor, pharmacist or other healthcare practitioner for advice. If any of the following happens, stop using LOCAL HEALTH OMEGA 3 and tell your doctor or pharmacist immediately, or go the casualty department at your nearest hospital: swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing, rash or itching, fainting. These are very serious side effects. If you have them, you may have had a serious reaction to LOCAL HEALTH OMEGA 3. You may need urgent medical attention or hospitalisation.

- **Frequent:** halitosis, fishy aftertaste and breath, heartburn, dyspepsia, nausea, loose stools, gastrointestinal upset.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you experience side effects, inform your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LOCAL HEALTH OMEGA 3.

5. How to store LOCAL HEALTH OMEGA 3

- Protect from moisture and store at or below 25 °C.
- KEEP OUT OF REACH OF CHILDREN.
- Do not use after the expiry date stated on the label.
- Return all unused LOCAL HEALTH OMEGA 3 to your pharmacist.
- Do not dispose of unused LOCAL HEALTH OMEGA 3 in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What LOCAL HEALTH OMEGA 3 contains

Each softgel capsule contains:

| | |
|--------------------------------------|---------|
| Fish Oil | 1000 mg |
| Of which Eicosapentaenoic Acid (EPA) | 180 mg |
| Of which Docosahexaenoic Acid (DHA) | 120 mg |

Other ingredients: bovine gelatin, glycerol, purified water.

Contains sugar: 40 mg glycerol per softgel capsule.

Presentation and identification of LOCAL HEALTH OMEGA 3

30/90 yellow softgel capsules packed into a white plastic container.

Holder of Certificate of Registration

Manufactured for: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, South Africa, 1685
Careline: 011 589 2729; careline@cjdsa.com; www.localhealth.co.za

This pamphlet was last revised in

Will be allocated by SAHPRA upon registration.

Registration number

Will be allocated by SAHPRA upon registration.

**PASIËNTINLIGTINGSBLAD
SKEDULERINGSSTATUS**

LOCAL HEALTH OMEGA 3 (sagte jelpkapsules)

Elke sagte jelpkapsule bevat:

| | |
|-----------------------------------|---------|
| Visolie | 1000 mg |
| Waarvan Eikosapentaenoësuur (EPS) | 180 mg |
| Waarvan Dokosaheksaënoësuur (DHS) | 120 mg |

Bevat suiker: 40 mg gliserol per sagte jelpkapsule.

Komplementêre Medisyne: Vette, Olies en Vetsure (Gesondheidsaanvulling)

Hierdie ongeregistreerde medisyne is nie deur SAHPRA vir gehalte, veiligheid of beoogde gebruik geëvalueer nie. Gesondheidsaanvullings dien slegs as aanvulling tot gesondheid of dieet.

Lees hierdie inligtingsblad noukeurig deur want dit bevat inligting wat belangrik is vir u.

LOCAL HEALTH OMEGA 3 is beskikbaar sonder 'n dokter se voorskrif, om u gesondheid te handhaaf. Nietemint moet LOCAL HEALTH OMEGA 3 versigtig gebruik word ten einde die beste resultate te verkry.

- Hou hierdie inligtingsblad. Dit kan nodig wees dat u dit weer lees.
- Moenie LOCAL HEALTH OMEGA 3 met enige ander persoon deel nie.
- Vra u gesondheidsorgpraktisyn of apteker indien u meer inligting of advies nodig het.

Wat is in hierdie inligtingsblad

1. Wat LOCAL HEALTH OMEGA 3 is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u LOCAL HEALTH OMEGA 3 gebruik.
3. Hoe om LOCAL HEALTH OMEGA 3 te gebruik.
4. Moontlike nuwe-effekte.
5. Berging van LOCAL HEALTH OMEGA 3.
6. Inhoud van die verpakking en ander inligting.

1. Wat LOCAL HEALTH OMEGA 3 is en waarvoor dit gebruik word

LOCAL HEALTH OMEGA 3 is 'n bron van omega-3-vetsure, EPS en DHS, wat kardiovaskulêre gesondheid en breinfunksie ondersteun, en om goeie gesondheid te handhaaf.

2. Wat u moet weet voordat u LOCAL HEALTH OMEGA 3 gebruik

Moet nie LOCAL HEALTH OMEGA 3 neem nie:

- Indien u allergies of sensitief is vir enige van die bestanddele gelys in afdeling 6.
- Indien u allergies is vir vis.

Waarskuwings en voorsorgmaatreëls

Raadpleeg 'n gesondheidsorgpraktisyn voordat u LOCAL HEALTH OMEGA 3 gebruik, veral as u 'n mediese toestand het. Gebruik LOCAL HEALTH OMEGA 3 met omsigtigheid en raadpleeg 'n gesondheidsorgpraktisyn voor gebruik:

- Indien u aan 'n bloedsingsversteuring ly of bloedverdunders gebruik.

Kinders en adolessente

LOCAL HEALTH OMEGA 3 word nie aanbeveel vir kinders jonger as 6 jaar nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik.

Die neem van LOCAL HEALTH OMEGA 3 en ander medisyne

Lig altyd u gesondheidsorgpraktisyn in indien u enige ander medisyne neem (dit sluit aanvullende of tradisionele medisyne in). Nie alle moontlike interaksies met ander medisyne word in hierdie pamflet ingesluit nie. Raadpleeg 'n gesondheidsorgpraktisyn voor gebruik. LOCAL HEALTH OMEGA 3 kan interaksie hê met die volgende medisyne: antistomiddels, aspirien, dipiridamol, anti-hipertensiewe middels.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of borsvoed, vermoed dat u swanger is of beplan om 'n baba te hê, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies voordat u LOCAL HEALTH OMEGA 3 gebruik.

Bestuur en die gebruik van masjinerie

Geen studies is uitgevoer oor die effekte op die vermoë om te bestuur of die gebruik van masjinerie nie. Pasiënte moet versigtig wees voordat hulle bestuur of masjinerie gebruik, totdat hulle redelik seker is dat LOCAL HEALTH OMEGA 3 nie hul werkverrigting nadelig beïnvloed nie.

3. Hoe om LOCAL HEALTH OMEGA 3 te gebruik

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie. Moenie die aanbeveelde daaglikse dosis oorskry nie. Gebruik LOCAL HEALTH OMEGA 3 presies soos aanbeveel in hierdie inligtingsblad, of soos aanbeveel deur u gesondheidsorgpraktisyn. Raadpleeg u gesondheidsorgpraktisyn indien u nie seker is nie.

Volwassenes en kinders 6 jaar en ouer:

Neem een tot drie (1-3) sagte jelpkapsules daaglik saam etes, of soos aanbeveel deur 'n gesondheidsorgpraktisyn.

4. Moontlike nuwe-effekte

LOCAL HEALTH OMEGA 3 kan nuwe-effekte hê. Nie alle nuwe-effekte vir LOCAL HEALTH OMEGA 3 is ingesluit in hierdie inligtingsblad nie. Indien u algemene gesondheid vererger, of as u enige ongewenste reaksies ervaar tydens die gebruik van LOCAL HEALTH OMEGA 3, raadpleeg u dokter, apteker of ander gesondheidsorgpraktisyn vir advies. As een van die volgende gebeur, hou op met die gebruik met LOCAL HEALTH OMEGA 3 en raadpleeg u dokter of apteker onmiddellik, of gaan na die ongevalle afdeling van u naaste hospitaal: swelling van jou hande, voete, enkels, gesig, lippe en mond of keel, wat dit moeilik kan maak om te sluk of asem te haal, veluitslag, gejuuk, of floutes. Hierdie is baie ernstige nuwe-effekte. Indien jy dit het, mag jy 'n ernstige allergiese reaksie op LOCAL HEALTH OMEGA 3 gehad het. Jy mag dringende mediese bystand of hospitalisasie nodig hê.

- **Dikwels:** halitose, visagtige nasmaak en visagtige asem, sooi-brand, dispepsie, naarheid, los ontlasting, gastrointestinale ongemak.

Lig asseblief u dokter of apteker in indien u enige nuwe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.

Rapportering van nuwe-effekte

Praat met u dokter of apteker as u nuwe-effekte ervaar. U kan ook nuwe-effekte by SAHPRA aanmeld via die "6.04 Adverse Drug Reactions Reporting Form", wat aanlyn gevind kan word onder SAHPRA se publikasies: <http://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 LOCAL HEALTH OMEGA 3.

5. Berging van LOCAL HEALTH OMEGA 3

- Beskerm teen vog en berg by of onder 25 °C.
- HOU BIJTE BEREIK VAN KINDERS.
- Moenie gebruik na die vervaldatum op die etiket nie.
- Neem alle ongebruikte LOCAL HEALTH OMEGA 3 na u apteker terug.
- Moenie ongebruikte LOCAL HEALTH OMEGA 3 in afvoerpype of rioolsisteme (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat LOCAL HEALTH OMEGA 3 bevat

Elke sagte jelpkapsule bevat:

| | |
|-----------------------------------|---------|
| Visolie | 1000 mg |
| Waarvan Eikosapentaenoësuur (EPS) | 180 mg |
| Waarvan Dokosaheksaënoësuur (DHS) | 120 mg |

Ander bestanddele: beesgelatien, gliserol, gesuiwerde water.

Bevat suiker: 40 mg gliserol per sagte jelpkapsule.

Aanbieding en identifikasie van LOCAL HEALTH OMEGA 3

30/90 geel sagte jelpkapsules, verpak in 'n wit plastiekhouer.

Houer van Registrasiesertifikaat

Vervaardig vir: CJ Distribution, 23 Stag Road, Glen Austin, Johannesburg, Suid Afrika, 1685
Sorglyn: 011 589 2729; careline@cjdsa.com; www.localhealth.co.za

Hierdie pamflet is laas hersien in

Sal met registrasie deur SAHPRA toegeken word.

Registrasienommer

Sal met registrasie deur SAHPRA toegeken word.