

PROFESSIONAL INFORMATION**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: SO**1. NAME OF THE MEDICINE**
BIOGEN OMEGA-3 1 000 mg FISH OIL (soft gelatine capsules)**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each soft gelatine capsule contains:

Fish oil	1 000 mg
Providing omega-3 fatty acids:	
Eicosapentaenoic acid (EPA)	180 mg
Docosahexaenoic acid (DHA)	120 mg
Vitamin E	12 mg

Sugar Free
Bovine Gelatine Capsules

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Soft Gelatine Capsule

4. CLINICAL PARTICULARS

4.1 BIOGEN OMEGA-3, a combination of fish oil and Vitamin E. Providing a source of omega-3 fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), for the maintenance of good health. Helps maintain and support cardiovascular health. Helps to support cognitive health and brain function. Helps support the development of the brain, eyes and nerves in children. The added Vitamin E contributes to the protection of cells from oxidative stress.

4.2 Posology and method of administration

Adults and children 6 years and older: Take 3 capsules daily, or as recommended by your or as recommended by a health care provider.

4.3 Contraindications:

- If you are allergic to seafood or fish.
- If you have a hypersensitivity to any of the excipients listed in 6.1.
- If you are allergic to any of the ingredients listed in 6.1.

4.4 Special warnings and precautions for use

Special care should be taken with BIOGEN OMEGA-3

- If you suffer from diabetes.
- If you suffer from a bleeding or blood clotting disorder.
- If you suffer from iron-deficiency anaemia or hyperthyroidism.

Stop taking BIOGEN OMEGA-3 at least two weeks before surgery, as it may interfere with bleeding during and after surgery.

Children and adolescents:

• BIOGEN OMEGA-3 is likely safe for children and adolescents. Consult with a healthcare practitioner prior to giving BIOGEN OMEGA-3 to children and adolescents under the age of 18.

Do not exceed the recommended daily dosage.

4.5 Interaction with other medicines and other forms of interaction

Fish oils may have interactions with other medicines. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use.

Anticoagulants/Anti-platelet medicines:

The use of fish oil and/or vitamin E with anticoagulants or anti-platelet agents may contribute to increased anticoagulant effects.

Anti-hypertensive medicines:

The use of fish oils in combination with anti-hypertensive agents may contribute to increased hypotensive effects.

Contraceptive medicines:

May decrease the triglyceride-lowering effects of fish oils.

Lipase inhibitors (Xenical, Orlistat):

Taking fish oil with lipase inhibitors might decrease the absorption of fish oil fatty acids. For best absorption, supplementation with fish oil fatty acids should be scheduled at least 2-4 hours apart.

Not all interactions with other medicines are included in this pamphlet.

4.6 Fertility, pregnancy and lactation

Safety in pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

BIOGEN OMEGA-3 can have side effects. Not all side effects reported for BIOGEN OMEGA-3 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while BIOGEN OMEGA-3, please consult your doctor, pharmacist or other healthcare practitioner for advice.

Immune system disorders

Frequency unknown: hypersensitivity reactions.

Nervous system disorders

Frequency unknown: headache, dizziness.

Gastrointestinal disorders

Frequency: gastrointestinal disturbances including abdominal bloating and pain or discomfort, indigestion, dyspepsia, flatulence, nausea and vomiting, diarrhoea or constipation, fishy breath, odour or aftertaste.

Skin and subcutaneous tissue disorders

Frequency unknown: skin rashes, itching and skin irritation.

If any of the following happens, stop using BIOGEN OMEGA-3 and tell your doctor or pharmacist immediately, or go to 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 BIOGEN OMEGA-3. You may need urgent medical attention or hospitalisation.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of BIOGEN OMEGA-3 is important. It allows continued monitoring of the benefit/risk balance of BIOGEN OMEGA-3. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the **Adverse Drug Reaction Reporting Form**, found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8).

In the event of overdose, treatment should be symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES**6. PHARMACEUTICAL PARTICULARS****6.1 List of excipients**

Gelatine, glycerine

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

24 Months.

6.4 Special precautions for storage

Store in a cool dry place, at or below 25 °C.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

400 ml PET Container
Pack sizes: 90 Soft Gelatine Capsules.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Biogen,
23 Stag Rd,
Glen Austin,
South Africa

8. REGISTRATION NUMBER

Will be allocated by SAHPRA upon registration.

9. DATE OF FIRST AUTHORISATION

Will be allocated by SAHPRA upon registration.

10. DATE OF REVISION OF THE TEXT

May 2021.

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PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

BIOGEN OMEGA-3 1 000 mg FISH OIL

Each soft gelatine capsule contains:

Fish oil	1 000 mg
Providing omega-3 fatty acids:	
Eicosapentaenoic acid (EPA)	180 mg
Docosahexaenoic acid (DHA)	120 mg
Vitamin E	12 mg

Sugar Free

Bovine Gelatine Capsules

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.

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

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

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

What is in this leaflet?

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

1. What BIOGEN OMEGA-3 is and what it is used for

BIOGEN OMEGA-3, a combination of fish oil and Vitamin E. Providing a source of omega-3 fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), for the maintenance of good health. Helps maintain and support cardiovascular health. Helps to support cognitive health and brain function. Helps support the development of the brain, eyes and nerves in children. The added Vitamin E contributes to the protection of cells from oxidative stress.

2. What you need to know before you take BIOGEN OMEGA-3

Do not take BIOGEN OMEGA-3:

- If you are allergic to seafood or fish.
- If you have a hypersensitivity to any of the ingredients of BIOGEN OMEGA-3 (see section 6).

Warnings and precautions

Take special care with BIOGEN OMEGA-3:

- If you suffer from diabetes.
- If you suffer from a bleeding or blood clotting disorder.
- If you suffer from iron-deficiency anaemia or hyperthyroidism.

Stop taking BIOGEN OMEGA-3 at least two weeks before surgery, as it may interfere with bleeding during and after surgery.

Children and adolescents:

- BIOGEN OMEGA-3 is likely safe for children and adolescents. Consult with a healthcare practitioner prior to giving BIOGEN OMEGA-3 to children and adolescents under the age of 18.

Do not exceed the recommended daily dosage.

Other medicines and BIOGEN OMEGA-3

Fish oils may interact with other medicines. Give your health care provider a list of all the medicines, herbs, non-prescription drugs, or dietary supplements you use.

Anticoagulants/Anti-platelet medicines:

The use of fish oil and/or vitamin E with anticoagulants or anti-platelet agents may contribute to increased anticoagulant effects.

Anti-hypertensive medicines:

The use of fish oils in combination with anti-hypertensive agents may contribute to increased hypotensive effects.

Contraceptive medicines:

May decrease the triglyceride-lowering effects of fish oils.

Lipase inhibitors (Xenical, Orlistat):

Taking fish oil with lipase inhibitors might decrease the absorption of fish oil fatty acids. For best absorption, supplementation with fish oil fatty acids should be scheduled at least 2-4 hours apart.

Not all interactions with other medicines are included in this pamphlet.

BIOGEN OMEGA-3 with food and drink

Essential nutrients are required by the human body to maintain an optimum nutritional status. These essential nutrients support health through its involvement in the biochemical processes in the human body by serving important structural and functional roles.

Dietary deficiency of essential nutrients may result in weakness, tiredness, decrease in vitality and can also contribute to the risk of developing illnesses and health problems.

Use this product in conjunction with food as part of a healthy, balanced diet, not as a substitute for such.

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 provider for advice before taking BIOGEN OMEGA-3.

Safety of BIOGEN OMEGA-3 during pregnancy and lactation has not been established.

Do not take BIOGEN OMEGA-3 while pregnant or breastfeeding.

Driving and using machinery

No studies on the effects on the ability to drive or use machinery have been performed. BIOGEN OMEGA-3 are generally well tolerated but caution is advised (see section 4).

3. How to take BIOGEN OMEGA-3

Do not share your medicines with any other person.

Always take BIOGEN OMEGA-3 exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults and children 6 years and older:

Take 3 capsules daily, or as recommended by your or as recommended by a health care provider.

If you take more BIOGEN OMEGA-3 than you should

In the event of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the rest of the BIOGEN OMEGA-3 with you so the doctor will know what you have taken.

If you forgot to take BIOGEN OMEGA-3

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BIOGEN OMEGA-3 can have side effects.

Not all side effects reported for BIOGEN OMEGA-3 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIOGEN OMEGA-3, please consult your healthcare practitioner for advice.

If any of the following happens, stop taking BIOGEN OMEGA-3 and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BIOGEN OMEGA-3. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Immune system disorders:

- Frequency unknown: Hypersensitivity reactions.

Nervous system disorders:

- Frequency unknown: Headache, dizziness.

Gastrointestinal disorders:

- Frequent: Gastrointestinal disturbances including abdominal bloating and pain or discomfort, indigestion, dyspepsia, flatulence, nausea and vomiting, diarrhoea or constipation, fishy breath, odour or aftertaste.

Skin and subcutaneous tissue disorders:

- Frequency unknown: Skin rashes, itching and skin irritation.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the 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 BIOGEN OMEGA-3.

5. How to store BIOGEN OMEGA-3

- Store at or below 25 °C.
- Protect from light and moisture.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BIOGEN OMEGA-3 contains

Each soft gelatine capsule contains:

Fish oil	1 000 mg
Providing omega-3 fatty acids:	
Eicosapentaenoic acid (EPA)	180 mg
Docosahexaenoic acid (DHA)	120 mg
Vitamin E	12 mg

The other ingredients are gelatine, glycerine.

What BIOGEN OMEGA-3 looks like and contents of the pack

Small round, white tablet, packed in a 400 ml PET container.

Pack sizes: 90 soft gelatine capsules.

Holder of certificate of registration

Biogen,

23 Stag Rd,

Glen Austin,

South Africa

This pamphlet was last revised in

May 2021.

Registration number

Will be allocated by SAHPRA upon registration.

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS:

BIOGEN OMEGA-3 1 000 mg FISH OIL

Elke sagte gelatienkapsule bevat:

Visolie	1 000 mg
Wat Omega-3 vetsure verskaf:	
Eikosapentaenoësuur (EPS)	180 mg
Dokosahexaenoësuur (DHS)	120 mg
Vitamin E	12 mg

Suiker

Beesgelatienkapsules

Aanvullende Medisyne: Gesondheidsaanvulling

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

Lees hierdie inligtingsblad aandagtydig deur want dit bevat inligting wat belangrik is vir jou.

BIOGEN OMEGA-3 is beskikbaar sonder 'n dokter se voorskrif, sodat jy jou gesondheid kan onderhou. Jy moet BIOGEN OMEGA-3 nietemin steeds versigtig neem om die beste resultate te verkry.

- Hou hierdie inligtingsblad aandagtydig.
- Do not share BIOGEN OMEGA-3 with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.

Wat is in hierdie inligtingsblad?

1. Wat is BIOGEN OMEGA-3 en waarvoor word dit gebruik.
2. Wat jy moet weet voor dat jy BIOGEN OMEGA-3 neem.
3. Hoe om BIOGEN OMEGA-3 te neem.
4. Moontlike newe-effekte.
5. Hoe om BIOGEN OMEGA-3 te bêre.
6. Inhoud van die pak en ander inligting

1. Wat is BIOGEN OMEGA-3 en waarvoor word dit gebruik

BIOGEN OMEGA-3, 'n kombinasie van visolie en vitamien E. Verskaf van 'n bron van omega-3-vetsure, Eikosapentaenoësuur (EPS) en Dokosahexaenoësuur (DHS) vir die behoud van goeie gesondheid. Dit kan help om kardiovaskulêre gesondheid te handhaaf en te ondersteun. Dit kan help om kognitiewe gesondheid en breinfunksie te ondersteun. Dit kan help met die ontwikkeling van die brein, oë en senuwees by kinders. Die toegevoegde vitamien E dra by tot die beskerming van sellie en tissuwee.

2. Wat jy moet weet voor dat jy BIOGEN OMEGA-3 neem

- Moenie BIOGEN OMEGA-3 met enigemand anders deel nie.
- Indien jy allergies is vir seekos of vis.
- Indien jy hipersensitief (allergies) is vir enige