

**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:** S0

**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**

*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 any of the following happens, stop using BIOGEN 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 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**

Essential nutrients are nutrients 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.

The 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.

**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.

<b>JOB:</b> BPS_Omega3 90s	<b>SIZE:</b> 246mm x 395mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
<b>COLOUR:</b>  K	<b>FINISHING:</b> <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Doming <input type="checkbox"/> Embossing
<b>PLEASE CHECK CAREFULLY</b> Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.	

