SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Omega 3 Fish Oil

2. Qualitative and quantitative composition

Each soft capsule Contains:

1000 mg Omega-3-Acid Ethyl Esters 90, comprising principally 840 mg ethylesters of eicosapentaenoic acid (EPA) (465 mg) and docosahexaenoic acid (DHA) (375 mg).

Excipient(s) with known effects

For the full list of excipients, see section 6.1

3. Pharmaceutical form

Soft gel capsule.

Oblong, transparent gelatin capsule containing pale yellow coloured oily liquid.

4. Clinical particulars

4.1 Therapeutic indications

Hypertriglyceridemia

Endogenous hypertriglyceridemia may require pharmacological intervention in addition to dietary modifications when adequate control is not achieved through diet alone:

- Type IV (Familial Hypertriglyceridemia): Monotherapy with fibrates or omega-3 fatty acids is often considered.
- Type IIb/III (Familial Combined Hyperlipidemia/Familial Dysbetalipoproteinemia): Combination therapy with statins and fibrates may be necessary when triglyceride levels remain inadequately controlled.

4.2 Posology and method of administration

Posology

Adults:

For the management of hypertriglyceridaemia, the initial recommended dose is two soft capsules daily. If an adequate response is not achieved, the dosage may be increased to four soft capsules daily.

To minimize gastrointestinal discomfort, it is advisable to take the capsules with food.

Special Populations

Elderly

There is limited clinical data regarding the use of Omega 3-acid-ethyl esters soft capsules in individuals over 70 years of age.

Renal Impairment

Limited clinical data are available concerning its in patients with renal impairment.

Hepatic Impairment

There is no information regarding its use in patients with hepatic impairment.

Children and Adolescents

The safety and efficacy of Omega 3-acid-ethyl esters in individuals under 18 years have not been established.

Method of Administration

For oral administration.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1

4.4 Special warnings and precautions for use

Warnings and Precautions

Patients receiving anticoagulant therapy should be monitored for bleeding time, especially when taking high doses (e.g., 4 capsules daily), as omega-3-acid ethyl esters may moderately increase bleeding time. Adjustments to anticoagulant dosage may be necessary (see section 4.5). The use of this medication does not eliminate the need for the usual surveillance required for patients on anticoagulants.

Caution is advised in patients at high risk of hemorrhage due to conditions such as severe trauma or surgery.

Patients with known sensitivity or allergy to fish should use this medication with caution.

Paediatric Population

The safety and efficacy of this medication in children and adolescents have not been established; therefore, its use is not recommended in this age group.

Atrial Fibrillation Risk

Systematic reviews and meta-analyses have indicated a dose-dependent increase in the risk of atrial fibrillation in patients with established cardiovascular diseases or risk factors treated with omega-3-acid ethyl esters compared to placebo. The highest observed risk occurs at a daily dose of 4 g. If atrial fibrillation develops, treatment should be permanently discontinued.

Older Adults

Clinical data on the use of omega-3-acid ethyl esters in individuals over 70 years of age are limited.

Renal Impairment

Limited clinical data are available regarding the use of omega-3-acid ethyl esters in patients with renal impairment.

Hepatic Impairment

Some patients have experienced a small but significant increase (within normal limits) in ASAT and ALAT levels. While no data suggest an increased risk for patients with hepatic impairment, monitoring of liver enzymes is recommended, particularly at higher doses (e.g., 4 capsules daily).

Exogenous Hypertriglyceridaemia

Omega-3-acid ethyl esters are not indicated for the treatment of exogenous hypertriglyceridaemia (type 1 hyperchylomicronaemia). Experience in secondary endogenous hypertriglyceridaemia, especially in uncontrolled diabetes, is limited.

Combination with Fibrates

There is no established experience regarding the use of omega-3-acid ethyl esters in combination with fibrates for the treatment of hypertriglyceridaemia.

4.5 Interaction with other medicinal products and other forms of interaction
Potential for amitriptyline to affect other medicinal products

Oral Anticoagulants

Omega-3-acid ethyl esters have been administered alongside warfarin without significant hemorrhagic complications. However, due to the potential for increased bleeding time, especially at higher doses (e.g., 4 capsules daily), patients receiving anticoagulant therapy should be closely monitored. The prothrombin time should be checked when initiating or discontinuing omega-3-acid ethyl esters therapy in patients on warfarin. Adjustments to the anticoagulant dosage may be necessary based on these monitoring results.

4.6 Fertility, pregnancy and lactation
Pregnancy

There are no adequate or well-controlled studies available on the use of omega-3-acid ethyl esters during pregnancy in humans; although animal studies have not demonstrated reproductive toxicity, the potential risk to the fetus is unknown, and therefore, use during pregnancy should be avoided unless clearly necessary.

Breast-feeding

As there are no data on whether omega-3-acid ethyl esters are excreted in human or animal breast milk, their use during lactation is not recommended.

Fertility

There are no available data on the effects of omega-3-acid ethyl esters on human fertility.

4.7 Effects on ability to drive and use machines

The effects of omega-3-acid ethyl esters on the ability to drive and operate machinery have not been specifically studied. However, omega-3-acid ethyl esters is expected to have little or no effect on the ability to drive or use machines

4.8 Undesirable effects

Adverse Reactions

The frequency of adverse reactions is classified as follows: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1000 to < 1/100), rare (≥ 1/10,000 to < 1/1000), and very rare (< 1/10,000).

Immune System Disorders

- Rare: Hypersensitivity

Metabolism and Nutrition Disorders

- Uncommon: Hyperglycaemia, Gout

Nervous System Disorders

- Uncommon: Dizziness, Dysgeusia, Headache

Cardiac Disorders

- Common: Atrial Fibrillation

Vascular Disorders

- Uncommon: Hypotension

Respiratory, Thoracic, and Mediastinal Disorders

- Uncommon: Epistaxis

Gastrointestinal Disorders

- Common: Gastrointestinal symptoms (including abdominal distension, abdominal pain, constipation, diarrhoea, dyspepsia, flatulence, eructation, gastro-oesophageal reflux disease, nausea, and vomiting)
- Uncommon: Gastrointestinal haemorrhage

Hepatobiliary Disorders

- Rare: Liver disorders (including increased transaminases, alanine aminotransferase, and aspartate aminotransferase)

Skin and Subcutaneous Tissue Disorders

- Uncommon: Rash
- Rare: Urticaria
- Not Known: Pruritus

Reporting of Suspected Adverse Reactions

It is essential to report any suspected adverse reactions following the authorization of this medicinal product. Reporting helps in the continued assessment of the benefit/risk balance of the medication. Healthcare professionals should report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

4.9 Overdose
No specific recommendations are provided. Treatment should be symptomatic.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Omega-3-triglycerides including other esters and acids.
ATC code: C10AX06.

The omega-3 series polyunsaturated fatty acids, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), are essential fatty acids.

Mechanism of action

Omega-3-acid ethyl esters 90 act on plasma lipids by reducing triglyceride levels, primarily through a decrease in VLDL (very low-density lipoprotein). This reduction in triglycerides is due to the decreased synthesis of triglycerides in the liver, as EPA and DHA are inefficient substrates for the enzymes involved in triglyceride synthesis. They also inhibit the esterification of other fatty acids. Additionally, an increase in peroxisomal β-oxidation of fatty acids in the liver further lowers triglycerides by reducing the availability of free fatty acids for synthesis.
The inhibition of triglyceride synthesis leads to a decrease in VLDL. In some patients with hypertriglyceridaemia, omega-3-acid ethyl esters 90 may cause an increase in LDL cholesterol. Although a small increase in HDL cholesterol may occur, this effect is less pronounced compared to fibrates and is not consistently observed.

The long-term effects of omega-3-acid ethyl esters on lipid levels, particularly after one year of treatment, are not well established. There is insufficient evidence to support that triglyceride reduction significantly reduces the risk of ischemic heart disease.
Omega-3-acid ethyl esters 90 have been shown to decrease thromboxane A2 production and slightly increase bleeding time, without significantly affecting other coagulation factors.

Clinical Efficacy and Safety
In the GISSI-Prevenzione study, a multicenter, randomized, open-label trial involving 11,324 patients who had a recent myocardial infarction (within 3 months) and were receiving preventive treatments, the effects of omega-3-acid ethyl esters 90 were evaluated. Patients were assigned to receive either omega-3-acid ethyl esters 90 (n=2836), vitamin E (n=2830), both omega-3-acid ethyl esters 90 and vitamin E (n=2830), or no treatment (n=2828).
Over a period of 3.5 years, patients receiving omega-3-acid ethyl esters 90 at a dose of 1g/day showed a significant reduction in a combined endpoint that included all-cause mortality, non-fatal myocardial infarction, and non-fatal stroke, with a relative risk reduction of 15% (p=0.0226). The combination of omega-3-acid ethyl esters 90 with or without vitamin E resulted in a relative risk reduction of 10% (p=0.0482). A significant reduction in non-fatal stroke was also observed, with a 20% relative risk reduction in patients taking omega-3-acid ethyl esters 90 alone (p=0.0082), and an 11% reduction in those taking omega-3-acid ethyl esters 90 with or without vitamin E (p=0.0526).

5.2 Pharmacokinetic properties
After absorption, omega-3 fatty acids follow three primary metabolic pathways:

a) They are transported to the liver, where they are incorporated into various lipoproteins and then distributed to peripheral lipid stores.

b) Omega-3 fatty acids replace phospholipids in cell membranes, where they serve as precursors for the production of various eicosanoids.

c) The majority of the fatty acids are oxidized to meet the body’s energy needs.

The levels of EPA and DHA in plasma phospholipids reflect the incorporation of these fatty acids into cell membranes.

Animal studies have demonstrated that the ethyl ester form of omega-3 fatty acids undergoes complete hydrolysis, with efficient absorption and incorporation of EPA and DHA into plasma phospholipids and cholesterol esters.

5.3 Preclinical safety data

Non-clinical data revealed no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction.

6. Pharmaceutical particulars

6.1 List of excipients

Capsule core:
Alpha-tocopherol

Capsule shell:
Gelatin Glycerol
Medium-chain triglycerides

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C. Protect from Light. Keep out of the reach of Children.

6.5 Nature and contents of container

Box containing 3 blister strips, each with 10 capsules (3×10)

6.6 Special precautions for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

GLPL Limited

India

8. Marketing authorisation number(s)

N/A

9. Date of first authorisation/renewal of the authorisation

N/A

10. Date of revision of the text

N/A