

SUMMARY OF PRODUCT CHARACTERISTICS. NAME OF THE MEDICINAL PRODUCT OLECOR 1000 mg soft capsules. QUALITATIVE AND QUANTITATIVE COMPOSITION. Each capsule contains: Active ingredient: 1000 mg of polyunsaturated fatty acid ethyl esters with an EPA and DHA content of not less than 85% in a 0.9 to 1.0 ratio to each other. For the excipients, see list of excipients. PHARMACEUTICAL FORM. Soft gelatin capsules. CLINICAL PARTICULARS. Therapeutic indications. Hypertriglyceridaemia. OLECOR is indicated for reducing high triglyceride levels when the response to diets and other non-pharmacological measures on their own is found to be inadequate. The treatment must always be associated with an adequate diet. Posology and method of administration. Hypertriglyceridaemia. Administration of one 1000 mg soft capsule 1 to 3 times a day is recommended according to medical prescription. Contraindications Known hypersensitivity to the product or any of its components. Generally contraindicated during pregnancy and lactation. Special warnings and precautions for use \_Keep out of the reach and sight of children. Special supervision is prudentially advisable in subjects with haemorrhagic diathesis and in treatments with anticoagulants, in which an altered increase in bleeding time may occur. Interaction with other medicinal products and other forms of interaction Concurrent use of the drug with anticoagulants may lead to a moderate increase in bleeding time.\_4.6 Pregnancy and lactation. Safety has not been established during pregnancy and lactation. Effects on ability to drive and use machines. OLECOR has no negative effects on the ability to drive and use machines. Undesirable effects. Mild transitory cases of nausea and diarrhoea have been observed. Overdose. No toxic effects from overdose are known. PHARMACOLOGICAL PROPERTIES. Pharmacodynamic properties. ATC: C10AX06. Triglyceride lowering agent Cardiovascular system. Once incorporated into membrane phospholipids, the EPA provided directly by the drug or which forms from the DHA competes with arachidonic acid as a substrate for the various enzymatic processes in blood platelets, the endothelium and leukocytes. This gives rise to greater endothelial relaxation, a reduction in platelet aggregability, and a decrease in chemotactic and pre-inflammatory power, thus having an antiatherosclerotic and antithrombotic effect.\_EPA and DHA, like other n-3 polyunsaturated acids, exert an antiarrhythmic action even at low doses, probably through a direct stabilizing effect on cardiomyocytes. The significant decrease in total and cardiovascular mortality (in sudden deaths in particular) observed in a vast prospective secondary prevention trial in

patients with previous myocardial infarction may be connected with this antiarrhythmic action. The favourable cardiovascular effects of EPA and DHA also include a reduction in plasma triglyceride, VLDL and fibrinogen levels, and increase in erythrocyte deformability with consequent decrease in blood viscosity. Pharmacokinetic properties. A labelled product has been used to study its absorption, excretion and distribution in tissues and plasma proteins in rats and dogs. More than 95% of the radioactivity is absorbed through the alimentary canal and a modest amount is excreted in urine as water-soluble material. Twenty-four hours after administration, about 35% of the radioactivity is found in tissues, especially in tissues involved in lipid metabolism. The plasma peak occurs at 3.40 hours in rats and 6.75 hours in dogs. The blood plasma fractions with the highest amounts of radioactivity are the VLDLs and chylomicrons. Clinical pharmacokinetic studies have confirmed that EPA and DHA ethyl esters are hydrolysed and incorporated into the various lipid fractions. After repeated administration, they provide EPA and DHA concentrations of the same order of magnitude as those obtainable by administering natural triglycerides. Preclinical safety data. Toxicological studies performed on the drug have ruled out toxic phenomena both in short and long term treatment at high doses. No teratogenic effects have been observed on animals or their fertility in reproduction studies. Carcinogenesis studies in rats have also shown that oral treatment for 24 months does not cause toxic or histopathological damage. PHARMACEUTICAL PARTICULARS. List of excipients di-\_tocopherol. Capsule covering constituents: gelatin succinate and glycerol. Incompatibilities. No incompatibilities with other drugs are known. Shelf life 18 months in unopened packaging. Special precautions for storage. Do not store at temperatures above 25°C. Nature and contents of container. PVC/PVDC/aluminium foil blister pack. Printed cardboard box. Pack of twenty 1000 mg soft capsules. MARKETING AUTHORIZATION HOLDER. MARKETING AUTHORIZATION NUMBER(S) 20 soft capsules. OLECOR 1000 mg soft capsules. ATC: C10AX06. Polyunsaturated fatty acid ethyl esters. COMPOSITION. Each capsule contains: Active ingredient: 1000 mg of polyunsaturated fatty acid ethyl esters with an EPA and DHA content of not less than 85% in a 0.9 to 1 ratio to each other. Excipients: di-\_tocopherol; capsule covering constituents: gelatin succinate and glycerol. HARMACEUTICAL FORM AND CONTENTS OLECOR 1000 mg soft capsules. Box of 20 soft capsules. PHARMACOTHERAPEUTIC GROUP. Triglyceride lowering agent - Cardiovascular system Marketing authorization holder. THERAPEUTIC INDICATIONS Hypertriglyceridaemia OLECOR is

indicated for reducing high triglyceride levels when the response to diets and other non-pharmacological measures on their own is found to be inadequate. The treatment must always be associated with an adequate diet.

**CONTRAINDICATIONS.** Known hypersensitivity to the product or any of its components. Generally contraindicated during pregnancy and lactation.

**PRECAUTIONS FOR USE.** Special supervision is prudentially advisable in subjects with haemorrhagic diathesis and in treatments with anticoagulants, in which a moderate increase in bleeding time may occur.

**SPECIAL WARNINGS.** Safety has not been established during pregnancy and lactation. Keep out of the reach and sight of children.

**POSODOLOGY AND METHOD OF ADMINISTRATION.** Hypertriglyceridaemia. The recommended dose is one 1000 mg soft capsule 1-3 times a day, according to medical prescription.

**UNDESIRABLE EFFECTS.** Mild transitory cases of nausea and diarrhoea have been observed. Compliance with the information found in the package leaflet reduces the occurrence of undesirable effects. Inform your doctor or pharmacist of any undesirable effect, even if it is not described in the package leaflet.

**EXPIRY AND STORAGE.** See the expiry date shown on the box. This date refers to the correctly stored product in unopened packaging. Do not store at temperatures above 25°C. Caution: do not use after the expiry date shown on the box. Keep out of the reach and sight of children.