

OMACOR 1000 MG CAPSULE, SOFT: PRESCRIBING INFORMATION

Presentation: Capsules containing 1000mg of omega-3-acid ethyl esters 90 comprising 840mg eicosapentaenoic acid ethyl ester (460mg) and docosahexaenoic acid ethyl ester (380mg).

Indications: Adjuvant treatment in secondary prevention after myocardial infarction.

Endogenous hypertriglyceridaemia as a supplement to diet when dietary measures alone are insufficient to produce an adequate response: Type IV in monotherapy; Type IIb/III in combination with statins, when control of triglycerides is insufficient. **Dosage and**

Administration: Post myocardial infarction: One capsule daily. Hypertriglyceridaemia: Initially two capsules daily. Increase to four capsules daily if necessary. May be taken with food. No or limited information of use in elderly (>70yrs), children, hepatic or renal impairment.

Contraindications, Warnings, Precautions etc: *Contraindications:* Hypersensitivity to ingredients including soya. *Warnings/Precautions:* Due to risk of haemorrhage (with high dose only) monitor patients on anticoagulant therapy and those at high risk of haemorrhage (e.g. severe trauma, surgery etc). Not recommended in children. Not indicated in exogenous hypertriglyceridaemia. There is limited experience in secondary endogenous hypertriglyceridaemia and no experience of use in combination with fibrates. In hepatic impairment, regularly monitor ASAT and ALAT. *Drug Interactions:* Monitor use with oral anticoagulants. **Pregnancy and Lactation:** Should not be used in pregnancy or lactation.

Ability to Drive and Operate Machinery: Not relevant. **Side Effects:** Common: dyspepsia, nausea. Uncommon: Abdominal pain, GI disorders, gastritis, gastroenteritis, hypersensitivity, dizziness, dysgeusia. Rare: GI pain, headache, hyperglycaemia, hepatic disorders, acne, pruritic rash, ill defined disorders. Very rare: Lower GI haemorrhage, hypotension, nasal dryness, urticaria, increased white blood cell count, increased blood lactate dehydrogenase, moderate elevation of transaminases in hypertriglyceridaemic patients. **Marketing**

Authorisation Holder: Pronova BioPharma Norge AS, P.O. Box 420, 1327 Lysaker, Norway.

PL: 15905/0001. **Basic NHS price:** £14.24 (28 capsules); £50.84 (100 capsules). **Legal**

Category: P. **Further information is available from:** Abbott Healthcare Products Ltd, Mansbridge Road, West End, Southampton, SO18 3JD. **Date of Last Review:** 10th June 2010.

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Abbott Healthcare Products Ltd by phone: 023 8046 7000 or email: medinfo.shl@abbott.com