1. NAME OF MEDICINAL PRODUCT
Omacor, 1000mg capsule, soft

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
One capsule contains:
Omega-3-acid ethyl esters 90
1000mg,
comprising eicosapentaenoic acid (EPA) ethyl ester (460mg) and docosahexaenoic acid (DHA) ethyl ester (380mg).
The total contents of Omega-3-acid ethyl esters is about 90%.
For the full list of excipients, see section "List of excipients".

3. PHARMACEUTICAL FORM
Capsule, soft.
Soft, oblong, transparent gelatin capsules containing pale yellow oil.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Post Myocardial Infarction
Adjuvant treatment in secondary prevention after myocardial infarction in addition to other standard therapy (e.g. statins, anti-platelet medicinal products, beta-blockers, ACE inhibitors).

Hypertriglyceridaemia
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.
Omacor is not indicated in exogenous hypertiglyceridaemia (type 1 hyperchylomicronaemia).

4.2 Posology and method of administration
Post Myocardial Infarction
One capsule daily.

Hypertriglyceridaemia
Initial treatment two capsules daily. If adequate response is not obtained, the dose may be increased to four capsules daily.
The capsules may be taken with food to avoid gastrointestinal disturbances.

There is no information regarding the use of Omacor in children and adolescents, in elderly patients over 70 years of age, or in patients with hepatic impairment (see section "Special warnings and precautions for use"), and only limited information regarding the use in patients with renal impairment.

4.3 Contraindications
Hypersensitivity to the active substance, to soya or to any of the excipients.

4.4 Special Warnings and Precautions for use
Because of the moderate increase in bleeding time (with the high dosage, i.e. 4 capsules), patients with bleeding disorders or receiving anticoagulant therapy or other drugs affecting coagulation (e.g. acetylsalicylic acid or NSAIDs) must be monitored and the dosage of anticoagulant adjusted if necessary (see section 4.5 "Interaction with other medicinal products and other forms of interaction").

In some patients a small but significant increase (within normal values) in ASAT and ALAT was reported, but there are no data indicating an increased risk for patients with hepatic impairment. ASAT and ALAT levels should be monitored in patients with any signs of liver damage (in particular with the high dosage, i.e 4 capsules)

4.5 Interaction with other medicinal products and other forms of interaction
Oral anticoagulants or other drugs affecting coagulation (e.g. acetylsalicylic acid or NSAIDs): See Section 4.4 Special warnings and precautions for use”.
Omacor has been given in conjunction with warfarin without haemorrhagic complications. However, the prothrombin time/International normalized ratio (PT/INR) must be checked when Omacor is combined with drug affecting PT/INR or when treatment with Omacor is stopped.

4.6 Pregnancy and Lactation
Pregnancy
There are no adequate data from the use of Omacor in pregnant women.
The potential risk for humans is unknown. Therefore Omacor should not be used during pregnancy unless clearly necessary.

Lactation
There are no data on the excretion of Omacor in human milk. Omacor should not be used during lactation.

4.7 Effects on ability to drive and use machines
Effects on ability to drive and use machines have not been studied. Nevertheless, Omacor is expected to have no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects
The frequencies of adverse reactions are ranked according to the following:
Very common (≥ 1/10);
Common (≥ 1/100 to < 1/10); uncommon (≥1/1000 to < 1/100); rare (≥ 1/10000 to < 1/1000); very rare ( < 1/10000)

Immune system disorders:
Rare: hypersensitivity

Metabolic and nutrition disorders:
Uncommon: hyperglycaemia, gout

Nervous system disorders:
Uncommon: dizziness, dysesthesia, headache

Vascular disorders:
Uncommon: hypotension

Respiratory thoracic and mediastinal disorders:
Uncommon: epistaxis
6.1 List of excipients

6.2 Incompatibilities
Capsule shell: gelatin, Glycerol, Purified water, Medium-chain triglycerides, Lecithin (soya)
Capsule core: alpha-tocopherol, phospholipids and cholesterol esters.

6.3 Shelf life
Not applicable.

6.4 Special precautions for storage
Do not store above 30ºC. Do not freeze.

6.5 Overdose
There are no special recommendations. Treatment should be symptomatic.

7. MANUFACTURER
The Netherlands
5048 AS Tilburg

8. DATE OF REVISION
Feb 2014