

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Omacor 1000 mg Soft Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One capsule contains

Omega-3-acid ethyl esters 90..... 1000 mg
comprising 840 mg eicosapentaenoic acid (EPA) ethyl ester (460 mg) and docosahexaenoic acid (DHA) ethyl ester (380 mg).

Excipient(s) with known effect:

May contain soya-bean oil

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft

Product imported from Spain

Soft, oblong, transparent gelatin capsules containing pale yellow oil.

4 CLINICAL PARTICULARS

As per PA1099/001/001

5 PHARMACOLOGICAL PROPERTIES

As per PA1099/001/001

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule core:

Alpha-tocopherol

Capsule shell:

Gelatin

Glycerol (E422)

Purified water

Medium-chain triglycerides

Lecithin (soya)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf life expiry date for this product shall be the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze.

6.5 Nature and contents of container

White bottle containing 28 capsules

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 PARALLEL PRODUCT AUTHORISATION HOLDER

PCO Manufacturing Ltd.
Unit 10, Ashbourne Business Park
Rath
Ashbourne
Co. Meath
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA0465/335/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th June 2014

10 DATE OF REVISION OF THE TEXT

April 2020