

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Omacor 1000mg Soft Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Omega-3-acid ethyl esters 90 1000 mg
Comprising 840 mg eicosapentaenoic acid (EPA) ethyl ester (460mg) and docosahexaenoic acid (DHA) ethyl ester (380mg)
for one capsule

Excipients: may contain soya bean oil

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft

Product imported from the UK:
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

alpha-tocopherol
gelatin
glycerol
purified water
medium-chain triglycerides
lecithin (soya)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The shelf life expiry date of this product is the date shown on the container and outer carton of the product as marketed 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 plastic container in a cardboard carton.
Pack size: 28 Capsules.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

Imbat Limited
Unit L2
North Ring Business Park
Santry
Dublin 9

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1151/134/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th June 2010

10 DATE OF REVISION OF THE TEXT

November 2014