

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Omacor 1000mg 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 (460mg) and docosahexaenoic acid (DHA) ethyl ester (380mg)

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule, soft

Product imported from Germany and 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, 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 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 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

IMED Healthcare Ltd.
Unit 625 Kilshane Avenue
Northwest Business Park
Ballycoolin
Dublin 15
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1463/042/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18th February 2011

10 DATE OF REVISION OF THE TEXT

June 2017