

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 (460mg) and
docosahexaenoic acid (DHA) ethyl ester (380mg) including also as antioxidant 4 mg
d-alpha-tocopherol (mixed with a vegetable oil e.g. soya oil).

For a 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

gelatin,
glycerol,
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 high density polyethylene (HDPE) bottle
1x28 capsules

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

LTT Pharma Limited
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8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1562/189/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 11th November 2016

10 DATE OF REVISION OF THE TEXT

December 2018