

PROFESSIONAL INFORMATION

SCHEDULING STATUS

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1 NAME OF THE MEDICINE

OPTIMEGA

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ingredients	Per capsule
Total Pharmaceutical Grade Fish oil, from tuna and deep marine fish oil providing:	823 mg
Docosahexaenoic Acid (DHA)	261 mg
Eicosapentaenoic Acid (EPA)	92 mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Yellow oblong, clear soft gel capsule.

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

OPTIMEGA is an omega-3 supplement for the maintenance of good health.

4.2 Posology and method of administration

One capsule daily with food, or as directed by a healthcare provider.

4.3 Contraindications

- Patient with hypersensitivity to any of the active or inactive ingredients.

4.4 Special warnings and precautions for use

- Use with caution in patients with haemorrhagic disorders or in patients using medication affecting blood coagulation, such as anticoagulants. (see **INTERACTIONS**)
- OPTIMEGA contains small amounts of sorbitol and glycerol which may have an effect on the glycaemic control of patients with *Diabetes Mellitus*.
- Patients with the rare hereditary condition of sorbitol or glycerol intolerance should not take this medicine.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed on OPTIMEGA. The following interactions are noted on monographs of the active ingredients:

- Anticoagulants/Antiplatelets: there is an increased risk of bleeding with concurrent use of medicines containing omega-3.

4.6 Fertility, pregnancy and lactation

OPTIMEGA is suitable for use during pregnancy and lactation at the discretion of a healthcare professional.

4.7 Effects on ability to drive and use machines

The effects on ability to drive and use machines has not been studied.

4.8 Undesirable effects

Possible side effects include

- gastrointestinal discomfort (nausea, vomiting, heartburn, abdominal pain, bloating, dyspepsia, diarrhoea, constipation)
- eructation (belching) associated with a fishy taste in the mouth

4.9 Overdose

Symptoms of overdosage include stomach upset, nausea, diarrhoea or constipation

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement
D34.6 Fats, Oils and fatty acids.

5.2 PHARMACOLOGICAL ACTION

Omega-3 contains Eicosapentaenoic Acid (EPA) and Docosahexaenoic Acid (DHA) which help to support cognitive health and brain function.

6 PHARMACEUTICAL PARTICULARS

Alpha-tocopherol (covitol), gelatine (bovine), lemon flavour, simethicone, purified water. Contains sugar: glycerol 0,11 g and sorbitol 0,013 g/capsule.

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Keep bottle tightly closed to protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

Blister packs with 10 capsules each, packed in cartons of 30, 60 or 90.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

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8 REGISTRATION NUMBER

To be allocated

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

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