

The Real Thing Mega Omega Fish Oil

Complementary Medicine. Health Supplement.

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS: S0

1 NAME OF THE MEDICINE

THE REAL THING MEGA OMEGA FISH OIL 1600 mg oil

THE REAL THING MEGA OMEGA FISH OIL lemon flavour 1600 mg oil

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THE REAL THING MEGA OMEGA FISH OIL contains:

	Per 5 ml	Per 7,5 ml
Omega-3 fish oil providing	1 600 mg	2 400 mg
EPA (eicosapentaenoic acid)	767 mg	1 150 mg
DHA (docosahexaenoic acid)	530 mg	795 mg
Other omega-3 fatty acids	303 mg	455 mg

The omega-3 fish oil is obtained from *Ammodytidae* (sandlance), *Carangidae* (mackerel), *Clupeidae* (herring, sardines), *Engraulidae* (anchovies), *Osmeridae* (smelts) and *Scombridae* (mackerel) (except the genera *Thunnus* (tunas) and *Sarda* (bonito)).

The inactive ingredient is a lemon flavour in the lemon variant. The oil is sugar free. For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

THE REAL THING MEGA OMEGA FISH OIL is a clear yellowish viscous liquid. The REAL THING MEGA OMEGA FISH OIL has a mild fish oil taste and odour. The lemon variant has a lemon flavour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

THE REAL THING MEGA OMEGA FISH OIL is a health supplement for -

- the maintenance of good health;
- helping to maintain/support cardiovascular health;
- helping reduce serum triglycerides/triacylglycerols;
- helping to support cognitive health and/or brain function;
- helping to support healthy development of brain, eyes and nerves in children up to 12 years of age.

Supplementation should not replace a healthy, balanced and varied diet.

4.2 Posology and method of administration

Adults and children 14 years and older: Take 1 to 1 ½ medicine measures (5 ml to 7,5 ml) orally daily, as required or as advised by your healthcare practitioner.

Children 9 to 14 years: Take 1 medicine measure (5 ml) orally daily.

Take with food and start with low dose while increasing dose gradually to help reduce gastrointestinal side effects.

Fish oil supplements can safely be used long term. Advise the patient to consult a healthcare provider for use beyond 6 months.

Paediatric population

THE REAL THING MEGA OMEGA FISH OIL has been shown to be safe in children 9 to 18 years.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

It contains concentrated omega-3 ethyl esters – fish (only for oral use).

Advise the patient to consult a healthcare practitioner before use:

- if the patient has a bleeding disorder.
- if the patient is taking blood thinning medicines.
- if the patient is asthmatic with sensitivity to aspirin.

A person suffering from fish and shell fish allergies should exercise caution when taking fish oil.

Hepatic function should be monitored in patients with hepatic impairment, particularly if receiving high doses of fish oil.

4.5 Interaction with other medicines and other forms of interaction

THE REAL THING MEGA OMEGA FISH OIL affecting other products:

Omega-3 fatty acids at high doses may have antiplatelet effects and should therefore be given with caution to patients on anticoagulant therapy.

4.6 Fertility, pregnancy and lactation

Advise the patient to consult a healthcare practitioner before taking THE REAL THING MEGA OMEGA FISH OIL during pregnancy and lactation. Safety has not been established. Docosahexaenoic acid (DHA) has been found in breast milk.

No fertility data is available.

4.7 Effects on ability to drive and use machines

THE REAL THING MEGA OMEGA FISH OIL has no or negligible influence on these abilities.

4.8 Undesirable effects

The most common adverse effects are gastrointestinal disturbances.

Summary of adverse reactions:

Nervous system disorders

Dizziness, headache, insomnia, fatigue and anxiety. Restlessness (rare) and formication (rare).

Vascular disorders

Haematological effects could include nose bleeds, increased low density lipoprotein (LDL) cholesterol levels (common).

Respiratory, thoracic and mediastinal disorders

Exacerbation of asthma and apnoea.

Gastrointestinal disorders

Gastro-intestinal disturbances may occur, especially potentially severe diarrhoea at high doses. Other disorders may include nausea (common), vomiting, belching (common), fishy aftertaste (common), metallic taste, fishy hiccups, fishy breath odour, fishy halitosis, bad breath (common), constipation, loose stools (common), diarrhoea (common), steatorrhea, anorexia, dry mouth, epigastric discomfort (common), abdominal pain (common), abdominal bloating, flatulence.

Fish oil can also cause acid reflux, heartburn (common) and dyspepsia.

Skin and subcutaneous tissue disorders

Skin rash (common), acne (rare), eczema (rare), itching, skin irritation.

Product issues

There is the possibility of vitamin E deficiency with long term use.
Frequencies of all adverse events are not known.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

Alternatively, suspected adverse reactions may be reported directly to the Holder of the Certificate of Registration, The Real Thing Food Supplements (Pty) Ltd, at telephone (021) 701-0244 or e-mail adr@therealthing.co.za

4.9 Overdose

DHA and EPA are possibly unsafe in high doses.

At high doses of fish oil (greater than 3 000 mg daily), blood coagulation may be decreased with a resultant increase in bleeding and stroke.

EPA at high doses (greater than 4 000 mg per day) have been linked to a greater risk of arrhythmias, atrial fibrillation or atrial flutter.

Doses of fish oil greater than 3 000 mg per day might suppress the immune response.

Fish oil supplements of 3 000 to 10 000 mg daily can increase low density lipoprotein (LDL) cholesterol levels in some patients by increasing the size of LDL particles.

There is the potential of severe diarrhoea at very high doses of fish oil.

Treatment of overdosage is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

THE REAL THING MEGA OMEGA FISH OIL belongs to category D Complementary Medicines, Health Supplements, class 34.6 Fats, Oils and Fatty Acids.

It is a source of essential fatty acids.

The omega-3 fatty acids that are found in fish oil, namely DHA (docosahexaenoic acid) and EPA (eicosapentaenoic acid), are long chain omega-3 polyunsaturated fatty acids. These essential fatty acids cannot satisfactorily be produced by the human body, hence they are obtained from foods or health supplements. DHA can be converted into EPA in humans.

Omega-3 polyunsaturated fatty acids are important for the maintenance of good health and play a role in the support and management of certain conditions in the human body.

There has been an increase in interest in marine oils following observations that populations with a diet rich in fish oils generally have a low incidence of cardiovascular disease. DHA and EPA have been found beneficial in promoting and maintaining a healthy cardiovascular system.

Fish oils help to reduce triglyceride levels in patients with hypertriglyceridemia.

DHA and EPA may help persons of all ages to improve their ability to concentrate, to learn and their memory function.

DHA and EPA contribute to the maintenance of neural function and normal vision.

5.2 Pharmacokinetics properties

The omega-3 fatty acids, DHA and EPA, found in fish oil are well absorbed after oral ingestion. After ingestion levels of DHA and EPA increase in blood, and are incorporated into most cells of the body including fat tissue, the brain, neural tissue and retina.

Paediatric population

No information is available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

The inactive ingredients include –

- lemon flavour
- nitrogen gas (head-space during packing).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

THE REAL THING MEGA OMEGA FISH OIL has a shelf life of 2 years when stored in a cool, dry place at or below 25 °C. Use within 60 days after opening.

6.4 Special precautions for storage

Store in an airtight container, protected from light. Refrigerate after opening.

6.5 Nature and contents of container

THE REAL THING MEGA OMEGA FISH OIL is packed in a 200 ml amber glass bottle with a non-child resistant 28 mm polypropylene white screw cap fitted with an LDPE insert. The bottle is packed in a round core carton fitted with a white insert lid.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

The REAL THING FOOD SUPPLEMENTS (PTY) LTD

9 Westlake Drive

Westlake 7945, Cape Town

Telephone: 021-701 0244

E-mail: info@therealthing.co.za

8 REGISTRATION NUMBERS

THE REAL THING MEGA OMEGA FISH OIL: (To be allocated)

THE REAL THING MEGA OMEGA FISH OIL lemon flavour: (To be allocated)

9 DATE OF FIRST AUTHORISATION

(To be allocated)

10 DATE OF REVISION OF TEXT

This is the first edition.