

The Real Thing Mega Omega Supreme Capsules

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 SUPREME CAPSULES, 823 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THE REAL THING MEGA OMEGA SUPREME CAPSULES contains:

| | Per capsule: | Per 2 capsules: |
|-----------------------------|--------------|-----------------|
| Omega-3 fish oil providing | 1 150 mg | 2 300 mg |
| EPA (eicosapentaenoic acid) | 422 mg | 844 mg |
| DHA (docosahexaenoic acid) | 287 mg | 574 mg |
| Other omega-3 fatty acids | 114 mg | 228 mg |

The omega-3 fish oil is obtained from *Engraulidae* (anchovies), *Clupeidae* (sardines), *Osmeridae* (smelt fish) and *Scombridae* and *Carangidae* (mackerels).

The capsules are sugar free. For full list of excipients, see section 6.1.

Excipients include Vitamin E (d-alpha tocopherol) as antioxidant, and a gelatine (bovine) capsule shell.

3 PHARMACEUTICAL FORM

THE REAL THING MEGA OMEGA SUPREME CAPSULES is a transparent soft gelatine capsule containing a pale yellow oil.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

THE REAL THING MEGA OMEGA SUPREME CAPSULES is a health supplement for –

- the maintenance of good health;
- helping to maintain/support cardiovascular health;
- helping to reduce serum triglycerides/triacylglycerols;
- helping to support cognitive health and/or brain function.

As a health supplement it should be combined with a varied diet.

4.2 Posology and method of administration

Adults 18 years and older: Take 2 capsules orally daily, as required or as advised by your healthcare practitioner.

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

Consult a healthcare practitioner before use beyond 6 months.

Paediatric population

Unsuitable for children under 18 years of age.

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 person to consult a healthcare practitioner before use if the person has a bleeding disorder, or is taking blood thinning medicines.

Caution is required if a person is asthmatic with sensitivity to aspirin.

Hepatic function should be monitored in patients with hepatic impairment.

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

4.5 Interaction with other medicines and other forms of interaction

THE REAL THING MEGA OMEGA SUPREME CAPSULES 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

Safety has not been established. Advise the patient to consult a healthcare practitioner before taking THE REAL THING MEGA OMEGA SUPREME CAPSULES during pregnancy and lactation. 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 SUPREME CAPSULES have a negligible influence on these abilities.

4.8 Undesirable effects

DHA or EPA derived from fish oil is generally well tolerated at the recommended dose. The most common adverse effects are gastrointestinal disturbances.

Summary of adverse reactions:

Nervous system disorders

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

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 apnea.

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, 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, acne (rare), eczema (rare), itching, skin irritation.

Product issues

There is a possibility of vitamin E deficiency with long term use, hence vitamin E (tocopherol) is included as an antioxidant.

Frequencies of all adverse reactions 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 3000 mg daily), blood coagulation may be decreased with a resultant increased risk in bleeding and stroke.

EPA at high doses (greater than 4000 mg per day) have been linked to a greater risk of arrhythmias, atrial fibrillation or atrial flutter.

Doses of fish oil greater than 3000 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 SUPREME CAPSULES 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 as nutritional substances for the maintenance of good health and play a role in the development and support of certain functions 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 contributes to the maintenance of neural function and normal vision.

5.2 Pharmacokinetic 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 excipients include:

- Vitamin E (D-alpha Tocopherol, 1000 IU/g) (as antioxidant);
- soft gelatine (bovine) capsule shells.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

THE REAL THING MEGA OMEGA SUPREME CAPSULES have a shelf life of 2 years when stored in a cool place, at or below 25 °C.

6.4 Special precautions for storage

Store in an airtight container. Protect from light.

6.5 Nature and contents of container

THE REAL THING MEGA OMEGA SUPREME CAPSULES is packed in a 200 ml amber glass bottle with a non-child resistant 45 mm polyethylene black screw cap fitted with an aluminium foil heat-induction or pressure tamper-evident seal. A silica gel sachet is included in the bottle. The bottle contains 60 capsules.

THE REAL THING MEGA OMEGA SUPREME CAPSULES is packed in a 400 ml amber glass bottle with a child resistant 53 mm polyethylene white screw cap fitted with an aluminium foil heat-induction or pressure tamper-evident seal. A silica gel sachet is included in the bottle. The bottle contains 150 capsules.

THE REAL THING MEGA OMEGA SUPREME CAPSULES is packed in a labelled container fitted with a metal base, and an AluPeel top with snap-on clear plastic lid. The container is lined with a clear plastic bag with 5 silica gel sachets included, and the bag is sealed. The container contains 900 capsules.

6.6 Special precautions for disposal

No special requirements.

7 HOLDER OF CERTIFICATE OF REGISTRATION

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