

# The Real Thing Mega Omega 3+6+9 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 3+6+9 CAPSULES contain omega-3 fatty acids 584 mg, omega-6 fatty acids 113 mg and omega-9 fatty acids 37 mg per capsule.

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THE REAL THING MEGA OMEGA 3+6+9 CAPSULES contain:

	Per capsule	Per 2 capsules
Omega-3 fish oil providing:	820 mg	1 640 mg
EPA (eicosapentaenoic acid)	300 mg	600 mg
DHA (docosahexaenoic acid)	203 mg	406 mg
Other omega-3 fatty acids	81 mg	162 mg
<i>Borago officinalis</i> (borage seed oil) providing:	228,4 mg	456,8 mg
Omega-6 LA (linoleic acid) Omega-6	73 mg	146 mg
GLA (gamma-linolenic acid)	40 mg	80 mg
Omega-9 oleic acid	37 mg	74 mg

The omega-3 fish oil is obtained from *Engraulidae* (anchovies).

The inactive ingredients include Vitamin E (d-alpha tocopherol) as antioxidant, and a gelatine (bovine) capsule shell. The capsules are sugar free. For full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

THE REAL THING MEGA OMEGA 3+6+9 CAPSULES is a transparent soft gelatine size 20 oblong capsule containing a pale yellow oil.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

THE REAL THING MEGA OMEGA 3+6+9 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.

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

### 4.2 Posology and method of administration

Adults 18 years and older: Take 2 capsules orally daily 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 of omega-3 fish oil.

Consult a healthcare practitioner before use beyond 6 months.

### **Paediatric population**

THE REAL THING MEGA OMEGA 3+6+9 CAPSULES is not indicated in paediatrics. 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 patient to consult a healthcare practitioner before use if the patient has a bleeding disorder, or is taking blood thinning medicines.

Caution is required if a patient 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.

Borage seed oil may increase the risk of bleeding by inhibiting platelet aggregation when used by patients with bleeding disorders. Patients should be advised to discontinue borage seed oil at least two weeks prior to an elective surgical procedure.

### **4.5 Interaction with other medicines and other forms of interaction**

THE REAL THING MEGA OMEGA 3+6+9 CAPSULES affecting other products:

Omega-3 fatty acids at high doses and borage seed oil supplementation 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 person to consult a healthcare practitioner prior to use if she is pregnant or breastfeeding. 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 3+6+9 CAPSULES may have a minor influence on the ability to drive and use machines due to possible undesirable effects.

### **4.8 Undesirable effects**

DHA or EPA derived from fish oil and borage seed oil are generally well tolerated at the recommended dose.

The most common adverse effects are gastrointestinal disturbances.

Summary of adverse reactions applicable to omega-3 fish oil:

#### *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, with 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.

Summary of adverse reactions applicable to borage seed oil:

#### *Gastrointestinal disorders:*

Belching (common), bloating (common), diarrhoea (common), soft stools (common).

Product issues:

There is a possibility of vitamin E deficiency with long term use, hence vitamin E (tocopherol) is included as 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](mailto: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 increased risk 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 3+6+9 CAPSULES belong 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.

Borage seed oil contains omega-6 and omega-9. Thus THE REAL THING MEGA OMEGA 3+6+9 CAPSULES contains all three omegas (3, 6 and 9) that beneficially help to promote good nutrition and health.

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 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.

Gamma linolenic acid in borage seed oil reaches peak plasma levels within 2,7 to 4,4 hours with oral ingestion.

## **Paediatric population**

No information is available.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

The inactive ingredients include:

- vitamin E (tocopherols as antioxidant);
- soft gelatine (bovine) capsule shells.

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

THE REAL THING MEGA OMEGA 3+6+9 CAPSULES have a shelf life of 2 years when stored in a cool, dry 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 3+6+9 CAPSULES are packed in a labelled, hard cardboard container fitted with a metal base and top, covered with a clear plastic lid. The container is lined with a clear plastic bag with a silica gel sachet included, and the bag is sealed. The container includes a foam sponge and contains 60 capsules.

Alternatively, THE REAL THING MEGA OMEGA 3+6+9 CAPSULES are 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.

### **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

Email: [info@therealthing.co.za](mailto:info@therealthing.co.za)

**8 REGISTRATION NUMBER**

(To be allocated)

**9 DATE OF FIRST AUTHORISATION**

(To be allocated)

**10 DATE OF REVISION OF THE TEXT**

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