

The Real Thing DHA 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 DHA CAPSULES, fatty acids 359 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

THE REAL THING DHA CAPSULES contains:

	Per capsule:	Per 2 capsules:	Per 4 capsules:
Omega-3 fish oil providing	500 mg	1 000 mg	2 000 mg
DHA (docosahexaenoic acid)	250 mg	500 mg	1 000 mg
EPA (eicosapentaenoic acid)	50 mg	100 mg	200 mg
and other omega-3 fatty acids	59 mg	118 mg	236 mg

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

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

The inactive ingredients include Vitamin E (d-alpha tocopherol) as antioxidant and a gelatin (bovine) capsule shell.

3 PHARMACEUTICAL FORM

THE REAL THING DHA CAPSULES is an oval softgel capsule, filled with an oily liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

THE REAL THING DHA CAPSULES is a health supplement for -

- The maintenance of good health;
- Helping to support cognitive health and/or brain function;
- Helping to support the development of the 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: Take 2 to 4 (two to four) capsules orally daily, as required or as advised by your health care practitioner.

Children 6 years and older: Take 1 to 2 (one to two) capsules orally daily, as required or as advised by your health care practitioner.

Advise patient to 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.

A patient should not exceed the daily dosage without consulting a health care practitioner. A health care practitioner must be consulted for use beyond 6 months.

Paediatric population

Capsules are not indicated in children under 6 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 triglycerides – fish (only for oral use).

Advise the patient to consult a health care practitioner before use if the patient has a bleeding disorder or is taking blood thinning medicines.

Caution is required if the patient is asthmatic with sensitivity to aspirin.

Hepatic function should be monitored in patients with hepatic impairment.

A patient suffering from fish allergies should exercise caution when taking fish oil.

4.5 Interaction with other medicines and other forms of interaction

THE REAL THING DHA CAPSULES affecting other medicines:

Fish oil 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 prior to use if she is pregnant or breastfeeding.

Docosahexaenoic acid (DHA) has been found in the infant in utero and in breast milk. No fertility data is available.

4.7 Effects on ability to drive and use machines

THE REAL THING DHA CAPSULES have a negligible influence on these abilities.

4.8 Undesirable effects

a. Summary of safety profile

The most common adverse effects are gastrointestinal disturbances.

b. List of adverse reactions

Nervous system disorders

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

Vascular disorders

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

Respiratory, thoracic and mediastinal disorders

Exacerbation of asthma and apnoea.

Gastrointestinal disorders

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

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

Skin and subcutaneous tissue disorders

Skin rash, acne (less frequent), eczema (less frequent), itching, skin irritation.

Product issues

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

The 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. Health care practitioners 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

With an overdose, side effects can be precipitated and/or be of increased severity.

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 (rare) 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 greater than 3 000 mg fish oil per day might cause immune suppression.

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.

In the event of overdose, advise the patient to stop taking the supplement. Treatment of overdosage is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

THE REAL THING DHA 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. Omega-3 polyunsaturated fatty acids are important as nutritional substances for the maintenance of good health and play a role in the prevention and management of certain conditions in the human body.

DHA and EPA may help patients of all ages to improve their ability to concentrate.

DHA is thought to be important for normal neural function, and might affect retinal, visual, learning and memory function.

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; incorporation into most cells of the body including fat tissue, the brain, neural tissue and the retina takes place.

Paediatric population

No information is available.

6 PHARMACEUTICAL PARTICULARS**6.1 List of excipients**

The inactive ingredients include:

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

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

THE REAL THING DHA 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 DHA CAPSULES are packed in a 200 ml amber glass bottle with a 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 120 capsules. 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

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8 REGISTRATION NUMBER

(To be allocated)

9 DATE OF FIRST AUTHORISATION

(To be allocated)

10 DATE OF REVISION OF THE TEXT

This is the first edition.