

The Real Thing Mega Omega Fish Oil

SCHEDULING STATUS: S0

THE REAL THING MEGA OMEGA FISH OIL and **THE REAL THING MEGA OMEGA FISH OIL** lemon flavour contain Omega-3 fish oil 1 600mg per 5 ml oil.
The oil is sugar free.

Complementary Medicine. Health Supplement.

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

Read all of this leaflet carefully because it contains important information for you
THE REAL THING MEGA OMEGA FISH OIL is available without a doctor's prescription, for you to maintain your health. Nevertheless you still need to use THE REAL THING MEGA OMEGA FISH OIL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share THE REAL THING MEGA OMEGA FISH OIL with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.

What is in this leaflet

1. What THE REAL THING MEGA OMEGA FISH OIL is and what it is used for
2. What you need to know before you take THE REAL THING MEGA OMEGA FISH OIL
3. How to take THE REAL THING MEGA OMEGA FISH OIL
4. Possible side effects
5. How to store THE REAL THING MEGA OMEGA FISH OIL
6. Contents of the pack and other information

1. What THE REAL THING MEGA OMEGA FISH OIL is and what it is used for
THE REAL THING MEGA OMEGA FISH OIL is a health supplement. It provides the following health benefits for adults and children:

- For the maintenance of good health;
- It helps to maintain and/or support a healthy heart and blood vessel system;
- It helps to reduce serum triglycerides (also known as triacylglycerols);
- It helps you to think, learn and remember, and other brain functions;
- It helps to support the healthy development of brain, eyes and nerves in children up to 12 years of age.

A varied diet is the most effective and safe way to achieve good nutrition, health, body composition, as well as mental and physical performance.

2. What you need to know before you take THE REAL THING MEGA OMEGA FISH OIL

Do not take THE REAL THING MEGA OMEGA FISH OIL

- If you are allergic or hypersensitive to any of the ingredients listed in section 6.

Warnings and precautions

Take special care with THE REAL THING MEGA OMEGA FISH OIL and consult a doctor before use:

- if you have a bleeding disorder or take medicines that cause bleeding;
- if you are asthmatic with a sensitivity to aspirin;
- if you have impaired liver function;

- if you are allergic to fish or shellfish.

Taking other medicines and THE REAL THING MEGA OMEGA FISH OIL

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

THE REAL THING MEGA OMEGA FISH OIL may affect other medicines:

- increase the activity of oral anticoagulants (medicines that cause bleeding) and should be used cautiously with these medicines.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or healthcare provider for advice before taking this medicine.

The safety of taking THE REAL THING MEGA OMEGA FISH OIL during pregnancy and breastfeeding is not known, therefore use cautiously or avoid. One of the omega-3 fatty acids, DHA is passed on to the baby during breastfeeding.

Driving and using machines

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

It is not always possible to predict to what extent THE REAL THING MEGA OMEGA FISH OIL may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which THE REAL THING MEGA OMEGA FISH OIL affects them.

3. How to take THE REAL THING MEGA OMEGA FISH OIL

Do not share medicines prescribed for you with any other person.

Always take THE REAL THING MEGA OMEGA FISH OIL exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The usual dose for adults and children 14 years and older: Take 1 medicine measure (5 ml) to 1 ½ medicine measures (7,5 ml) orally daily.
- The usual dose for children 9 to 14 years: Take 1 medicine measure (5 ml) orally daily.
- Take with food and start with a low dose while increasing the dose gradually to help reduce side effects.
- Consult a health care practitioner before use beyond 6 months.

If you take more THE REAL THING MEGA OMEGA FISH OIL than you should

Too much fish oil might:

- Increase the risk of bleeding;
- Cause irregular heart beat;
- Suppress your immune response;
- Increase low density lipoprotein (LDL) cholesterol levels in some patients;
- Cause severe diarrhoea at very high doses.

Treat any symptoms that may occur. In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at your nearest hospital or poison centre.

If you forget to take THE REAL THING MEGA OMEGA FISH OIL

If you forget to take it for a day or two, just start again at the regular daily dose. Do not take a double dose to make up for the forgotten individual doses.

If you stop taking THE REAL THING MEGA OMEGA FISH OIL

You may not achieve optimal benefits if you do not take it regularly.

4. Possible side effects

THE REAL THING MEGA OMEGA FISH OIL can have side effects.

Not all side effects reported for it are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking THE REAL THING MEGA OMEGA FISH OIL, please consult your healthcare provider for advice.

If any of the following happens, stop taking THE REAL THING MEGA OMEGA FISH OIL and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Skin rash
- Acne (less frequent)
- Eczema (less frequent)
- Itching
- Skin irritation

These are all very serious side effects. If you have them, you may have had a serious reaction to THE REAL THING MEGA OMEGA FISH OIL. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Nose bleeds
- Increased low density lipoprotein (LDL) cholesterol levels (frequent)
- Asthma worsening
- Slowed or erratic breathing during your sleep (apnoea)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Nausea
- Burping
- Fishy aftertaste
- Loose stools
- Epigastric discomfort
- Abdominal pain
- Heartburn
- Bad breath

Less frequent side effects:

- Restlessness
- Formication (sensation of fictitious bugs crawling over you)

Frequencies not known:

- Dizziness
- Headache
- Insomnia
- Fatigue (tiredness)
- Anxiety
- Diarrhoea, severe at high doses
- Vomiting
- Metallic taste
- Fishy hiccups
- Fishy breath odour
- Fishy halitosis
- Constipation
- Foul smelling oily stools
- Anorexia
- Dry mouth

- Abdominal bloating
- Flatulence
- Acid reflux
- Dyspepsia
- Possibility of vitamin E deficiency with long term use of omega-3 fatty acids.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects 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> By reporting side effects, you can help provide more information on the safety of THE REAL THING MEGA OMEGA FISH OIL.

Or side effects can be reported directly to The Real Thing Food Supplements (Pty) Ltd, at telephone (021) 701-0244 or e-mail adr@therealthing.co.za

5. How to store THE REAL THING MEGA OMEGA FISH OIL

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

- Store in a cool, dry place at or below 25 °C.
- Store in an airtight container.
- Keep the container tightly closed.
- Protect from light.
- Do not store in the bathroom.
- Refrigerate after opening and use within 60 days.
- Do not use after the expiry date stated on the label or container.

Do not use THE REAL THING MEGA OMEGA FISH OIL if you notice a cloudy and splotchy appearance, an unusually strong fishy smell or experience an unusually unpleasant aftertaste from date of opening.

Return any unused or expired medicine to your pharmacist for proper disposal.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What THE REAL THING MEGA OMEGA FISH OIL contains

- The active substances are:

	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 other ingredients include a head-space gas i.e. nitrogen gas, and the lemon variant includes a lemon flavour.

THE REAL THING MEGA OMEGA FISH OIL is available as an unflavoured and a lemon flavoured oil.

What THE REAL THING MEGA OMEGA FISH OIL looks like and contents of the pack

THE REAL THING MEGA OMEGA FISH OIL is a clear yellowish viscous liquid. There is a mild fish oil taste and odour.

THE REAL THING MEGA OMEGA FISH OIL lemon flavour is a clear yellowish viscous liquid. It has a lemon flavour.

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.

Holder of Certificate of Registration

THE REAL THING FOOD SUPPLEMENTS (PTY) LTD

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This leaflet was last revised in

This is the first edition.

Registration numbers

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

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

Access to the corresponding Professional Information

The Professional Information is located at: <https://www.therealthing.co.za/index.php/the-range/fish-oil/12-the-real-thing/89-mega-omega-liquid>

Or obtain the Professional Information directly from THE REAL THING FOOD SUPPLEMENTS (PTY) LTD using the contact details listed under Holder of Certificate of Registration.

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