

THE REAL THING MEGA OMEGA 3+6+9 CAPSULES

SCHEDULING STATUS: S0

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.

The capsules are 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 3+6+9 CAPSULES is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use THE REAL THING MEGA OMEGA 3+6+9 CAPSULES 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 3+6+9 CAPSULES with any other person.
- Ask your healthcare practitioner or pharmacist if you need more information or advice.

What is in this leaflet

1. What THE REAL THING MEGA OMEGA 3+6+9 CAPSULES is and what it is used for
2. What you need to know before you take THE REAL THING MEGA OMEGA 3+6+9 CAPSULES
3. How to take THE REAL THING MEGA OMEGA 3+6+9 CAPSULES
4. Possible side effects
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6. Contents of the pack and other information

1. What THE REAL THING MEGA OMEGA 3+6+9 CAPSULES is and what it is used for
THE REAL THING MEGA OMEGA 3+6+9 CAPSULES is a health supplement. It offers the following health benefits for adults:

- It helps to maintain 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.

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 3+6+9 CAPSULES

Do not take THE REAL THING MEGA OMEGA 3+6+9 CAPSULES:

- 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 3+6+9 CAPSULES and consult a doctor before use:

- if you have a bleeding disorder or take medicine that causes bleeding;
- if you are an asthmatic with a sensitivity to aspirin;
- if you have impaired liver function;
- if you are allergic to fish or shellfish.

Taking other medicines with THE REAL THING MEGA OMEGA 3+6+9 CAPSULES:

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

THE REAL THING MEGA OMEGA 3+6+9 CAPSULES may affect other medicines:

- Increase the activity of oral anticoagulants (medicines that cause bleeding) and should be used cautiously or not at all with these medicines.

Pregnancy and breastfeeding:

The safety of taking THE REAL THING MEGA OMEGA 3+6+9 CAPSULES during pregnancy and breastfeeding is not known, therefore use cautiously or avoid. One of the omega-3 fatty acids, DHA, has been found in breastmilk.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or healthcare practitioner for advice before taking this medicine.

Driving and using machines

THE REAL THING MEGA OMEGA 3+6+9 CAPSULES may have a minor influence on these abilities.

It is not always possible to predict to what extent THE REAL THING MEGA OMEGA 3+6+9 CAPSULES 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 3+6+9 CAPSULES affects them.

THE REAL THING MEGA OMEGA 3+6+9 CAPSULES contain vitamin E (d-alpha tocopherol) as antioxidant and soft gelatine (bovine) capsule shells.

3. How to take THE REAL THING MEGA OMEGA 3+6+9 CAPSULES

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

Always take THE REAL THING MEGA OMEGA 3+6+9 CAPSULES 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 18 years and older is:

- Take 2 capsules orally daily, as required or as advised by your healthcare practitioner.
- Take with food and start with a low dose while increasing the dose gradually to help reduce side effects.
- Consult a healthcare practitioner for use beyond 6 months.

If you take more THE REAL THING MEGA OMEGA 3+6+9 CAPSULES than you should

Too much fish oil may:

- Increase the risk of bleeding;
- Cause irregular heart beat;
- Suppress your immune system;
- 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 control centre.

If you forget to take THE REAL THING MEGA OMEGA 3+6+9 CAPSULES

If you have forgotten to take THE REAL THING MEGA OMEGA 3+6+9 CAPSULES 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 3+6+9 CAPSULES

You may not achieve optimal benefits if you do not take THE REAL THING MEGA OMEGA 3+6+9 CAPSULES regularly.

4. Possible side effects

THE REAL THING MEGA OMEGA 3+6+9 CAPSULES can have side effects.

Not all side effects reported for THE REAL THING MEGA OMEGA 3+6+9 CAPSULES are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking THE REAL THING MEGA OMEGA 3+6+9 CAPSULES, please consult your healthcare practitioner for advice.

If any of the following happens, stop taking THE REAL THING MEGA OMEGA 3+6+9 CAPSULES 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 allergic reaction to THE REAL THING MEGA OMEGA 3+6+9 CAPSULES. 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

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
- Bloating

- Diarrhoea
- Soft stools

Less frequent side effects:

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

Frequencies not known:

- Dizziness
- Headache
- Insomnia
- Fatigue (tiredness)
- Anxiety
- Vomiting
- Metallic taste
- Fishy hiccups
- Fishy breath odour
- Fishy halitosis
- Constipation
- Foul smelling oily stools
- Anorexia
- Dry mouth
- Flatulence
- Acid reflux
- Dyspepsia
- 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 Reaction 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 3+6+9 CAPSULES.

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 3+6+9 CAPSULES

Store all medicines out of the 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 a bathroom.
- Do not use after the expiry date stated on the label or container.

Do not use THE REAL THING MEGA OMEGA 3+6+9 CAPSULES if you notice the capsules have discoloured from date of opening.

Return all unused or expired medicine to your pharmacist.

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 3+6+9 CAPSULES contain

- The active substances are:

	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
and other omega-3 fatty acids	81 mg	162 mg
Borage seed oil providing	228,4 mg	456,8 mg
Omega-6 LA (linoleic acid)	73 mg	146 mg
Omega-6 GLA (gamma-linolenic acid)	40 mg	80 mg
Omega-9 oleic acid	37 mg	74 mg

- The other ingredients are: vitamin E (d-alpha tocopherol) as antioxidant, and a soft gelatine (bovine) capsule shell.

What THE REAL THING MEGA OMEGA 3+6+9 CAPSULES look like and contents of the pack

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

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.

Holder of Certificate of Registration

THE REAL THING FOOD SUPPLEMENTS (PTY) LTD

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Registration number

(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/90-mega-omega-369>

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.