

The Real Thing DHA Capsules

SCHEDULING STATUS: S0

THE REAL THING DHA CAPSULES contain the active substance: **Omega fish oil 500 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 DHA CAPSULES are available without a doctor's prescription, for you to maintain your health. Nevertheless you still need to use THE REAL THING DHA 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 DHA CAPSULES 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 DHA CAPSULES is and what it is used for
2. What you need to know before you take THE REAL THING DHA CAPSULES
3. How to take THE REAL THING DHA CAPSULES
4. Possible side effects
5. How to store THE REAL THING DHA CAPSULES
6. Contents of the pack and other information

1. What THE REAL THING DHA CAPSULES is and what it is used for

THE REAL THING DHA CAPSULES is a health supplement that provides nutrition in the form of omega-3 fatty acids. It offers the following health benefits for adults and children:

- It is for the maintenance of good health;
- It helps support cognitive health (the ability to think clearly and have a good memory) and/or brain function;
- It helps to support the development of the brain, the 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 DHA CAPSULES

Do not take THE REAL THING DHA CAPSULES:

- if you are allergic or hypersensitive to Omega-3 oil or to any of the ingredients (listed in section 6). Take note that the active substance is derived from fish.

Warnings and precautions

Take special care with THE REAL THING DHA CAPSULES:

- if you have a bleeding disorder or take medicine that thins the blood;
- if you have asthma and also are sensitive to aspirin;
- if you have liver impairment;
- if you are allergic to fish.

Other medicines and THE REAL THING DHA CAPSULES:

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

THE REAL THING DHA CAPSULES may affect other products:

- Fish oil at high doses may have antiplatelet effects and should therefore be given with caution to patients on anticoagulants (medicines that cause bleeding).

THE REAL THING DHA CAPSULES with food and drink:

Refer to section 3, how to take this medicine.

Pregnancy and breastfeeding:

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

The safety of taking THE REAL THING DHA CAPSULES during pregnancy and breastfeeding is not known, therefore use cautiously or avoid. One of the omega-3 fatty acids, DHA, is found in the baby's bloodstream while in the mother's uterus and is also passed on to the baby during breastfeeding.

Driving and using machines

THE REAL THING DHA CAPSULES may have a negligible influence on these abilities. It is not always possible to predict to what extent THE REAL THING DHA CAPSULES may interfere with the daily activities of a person. Persons should ensure that they do not engage in the above activities until they are aware of the measure to which THE REAL THING DHA CAPSULES affects them.

3. How to take THE REAL THING DHA CAPSULES

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

Always take THE REAL THING DHA 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 is:

- For adults: Take 2 to 4 capsules orally daily, as required or as advised by your health care provider.
- For children 6 years and older: Take 1 to 2 capsules orally daily, as required or as advised by your health care provider.
- Take with food to help reduce side effects.
- Start with a low dose and increase the dose gradually to help reduce gastrointestinal side effects.
- Do not take more than the recommended dose, unless under direct supervision of your doctor.
- Can be taken for as long as 6 months, after which you need to consult your health care provider.

If you have a medical condition, check with your doctor before taking any supplement.

If you take more THE REAL THING DHA CAPSULES than you should

More severe side effects may occur if you have taken too much THE REAL THING DHA CAPSULES.

Too much fish oil may:

- Increase the risk of bleeding;
- Cause irregular heart beat or rapid heartbeat;
- Cause suppression of your immune system;
- Increase blood cholesterol levels;
- Cause severe diarrhoea.

If you are not feeling well, stop taking the supplement and consult your doctor. Treat any symptoms that may occur.

In the event of overdosage, stop taking the supplement and consult your doctor or pharmacist. If neither is available, seek help at your nearest hospital or poison centre. Take this leaflet and the product container with you for identification.

If you forget to take THE REAL THING DHA CAPSULES

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 DHA CAPSULES

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

4. Possible side effects

THE REAL THING DHA CAPSULES 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 DHA CAPSULES, please consult your health care provider for advice.

If any of the following happens, stop taking THE REAL THING DHA CAPSULES and tell your doctor immediately or go to the casualty department at your nearest hospital. Take this information leaflet with you.

- 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 DHA 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:

- Asthma
- Apnoea (repeatedly stopping and starting breathing during 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
- Belching
- Fishy aftertaste
- Bad breath, halitosis
- Loose stools
- Diarrhoea
- Epigastric (upper stomach area) discomfort
- Abdominal (stomach area) pain
- Heartburn
- Cholesterol

Less frequent side effects:

- Restlessness
- Formication (feeling of bugs crawling on your skin)

Unknown frequency:

- Dizziness
- Headache

- Insomnia (sleeplessness)
- Fatigue (tiredness)
- Anxiety (feeling stressed)
- Nose bleeds
- Vomiting
- Metallic taste
- Fishy hiccups
- Fishy breath odour
- Constipation
- Anorexia (low body weight due to not eating)
- Dry mouth
- Abdominal bloating (stomach area filled with gas)
- Flatulence (gas in intestines)
- Steatorrhea (excess fat in faeces)
- Acid reflux (stomach acid comes up towards your throat)
- Dyspepsia (discomfort in upper stomach area)
- Vitamin E deficiency (with long term use)

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 DHA CAPSULES.

Alternatively, side effects may 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 DHA 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 use after the expiry date stated on the label or container.

Do not use THE REAL THING DHA 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 DHA CAPSULES contain

- The active substances are:

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

What THE REAL THING DHA CAPSULES look like and contents of the pack

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

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/13-the-real-thing/the-range/96-dha120>

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.