PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

GENOLOGIX OMEGA 3 FISH OIL 1500mg soft capsules

Fish oil 36:24 TG 2 500 mg per daily dose (2 soft capsules), providing eicosapentaenoic acid (EPA) 900 mg and docosahexaenoic acid (DHA) 600 mg (1 500 mg omega-3 fatty acids)

Sugar free

COMPLEMENTARY MEDICINE

Health Supplement

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

This leaflet is also available in Afrikaans on the product pages at https://genologix.co.za/product/genologix-omega-3-fish-oil-softgels-30-days-supply/ (30-day pack) and https://genologix.co.za/product/genologix-omega-3-fish-oil-softgels-bulk-120-days-supply/ (120-day pack).

Read all of this leaflet carefully because it contains important information for you

Genologix Omega 3 Fish Oil 1500mg is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use Genologix Omega 3 Fish Oil 1500mg carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share Genologix Omega 3 Fish Oil 1500mg 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 Genologix Omega 3 Fish Oil 1500mg is and what it is used for
2. What you need to know before you take Genologix Omega 3 Fish Oil 1500mg
3. How to take Genologix Omega 3 Fish Oil 1500mg
4. Possible side effects
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6. Contents of the pack and other information

1. What Genologix Omega 3 Fish Oil 1500mg is and what it is used for

Genologix Omega 3 Fish Oil 1500mg is a health supplement. It contains concentrated fish oil, a source of the omega-3 fatty acids EPA (eicosapentaenoic acid) and DHA (docosahexaenoic acid).

The fish oil is in natural triglyceride (TG) form, the same form found in fish.

Genologix Omega 3 Fish Oil 1500mg:

- is a source of omega-3 fatty acids (EPA and DHA) for the maintenance of good health;
- helps maintain and support cardiovascular (heart) health;
- helps to reduce serum triglycerides (a type of fat in the blood); and
- helps support cognitive health and brain function.

2. What you need to know before you take Genologix Omega 3 Fish Oil 1500mg

Do not take Genologix Omega 3 Fish Oil 1500mg:

- if you are hypersensitive (allergic) to fish, fish oil, gelatine or any of the other ingredients of Genologix Omega 3 Fish Oil 1500mg (listed in section 6).

Warnings and precautions

Take special care with Genologix Omega 3 Fish Oil 1500mg. Talk to your doctor or pharmacist before taking it:

- if you have a bleeding disorder;
- if you take medicines that thin the blood (see "Other medicines and Genologix Omega 3 Fish Oil 1500mg");
- if you have asthma and are sensitive to aspirin;
- if you are going to have an operation or dental surgery; or
- if you have diabetes or liver disease.

Genologix Omega 3 Fish Oil 1500mg is derived from seafood.

Children and adolescents

Do not give Genologix Omega 3 Fish Oil 1500mg to children and adolescents under 18 years of age. Its safety in this age group has not been established.

Other medicines and Genologix Omega 3 Fish Oil 1500mg

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

Omega-3 fatty acids may increase the effect of medicines that thin the blood or prevent blood clots, such as:

- warfarin,
- aspirin or clopidogrel,
- other anti-inflammatory medicines (NSAIDs, e.g. ibuprofen).

Omega-3 fatty acids may slightly lower blood pressure. Talk to your health care provider if you take medicine for high blood pressure.

Genologix Omega 3 Fish Oil 1500mg with food, drink and alcohol

Take Genologix Omega 3 Fish Oil 1500mg with food. This helps your body absorb the oil and reduces the chance of a fishy aftertaste or stomach upset.

Pregnancy, breastfeeding and fertility

Genologix Omega 3 Fish Oil 1500mg is not intended for use during pregnancy or breastfeeding. If you are pregnant or breastfeeding, consult your health care provider before taking it.

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.

Driving and using machines

Genologix Omega 3 Fish Oil 1500mg is not expected to affect your ability to drive or use machines.

It is not always possible to predict to what extent Genologix Omega 3 Fish Oil 1500mg may interfere with your daily activities. Do not drive, operate machinery or take part in activities that need you to be alert until you know how Genologix Omega 3 Fish Oil 1500mg affects you.

Genologix Omega 3 Fish Oil 1500mg contains fish, bovine gelatine and sulphites

Genologix Omega 3 Fish Oil 1500mg is made from fish oil. Do not take it if you are allergic to fish. The soft capsule shell is made from bovine (beef) gelatine, so it is not suitable for vegetarians or vegans. The fish oil may contain very small amounts of sulphites. It contains no sugar and no sweeteners.

3. How to take Genologix Omega 3 Fish Oil 1500mg

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

Always take Genologix Omega 3 Fish Oil 1500mg 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.

Adults (18 years and older): take two (2) soft capsules once a day. This provides 900 mg of EPA and 600 mg of DHA.

Do not take more than two (2) soft capsules in 24 hours.

Children and adolescents under 18 years: Genologix Omega 3 Fish Oil 1500mg is not intended for this age group.

How to take it:

1. Take the soft capsules with food.
2. Swallow the soft capsules whole with a glass of water. Do not chew or open them.
3. You may take both capsules together, or one with breakfast and one with dinner.
4. Stop taking Genologix Omega 3 Fish Oil 1500mg if you get any side effects (see section 4).

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

If you take more Genologix Omega 3 Fish Oil 1500mg than you should

If you take too many soft capsules, you may get stomach upset, nausea, loose stools or diarrhoea. Very high doses may increase the risk of bleeding.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take Genologix Omega 3 Fish Oil 1500mg

If you forget a dose, take your next dose at the usual time the next day.

Do not take a double dose to make up for a forgotten dose.

If you stop taking Genologix Omega 3 Fish Oil 1500mg

You can stop taking Genologix Omega 3 Fish Oil 1500mg at any time. No withdrawal effects are expected.

4. Possible side effects

Genologix Omega 3 Fish Oil 1500mg can have side effects.

Not all side effects reported for Genologix Omega 3 Fish Oil 1500mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Genologix Omega 3 Fish Oil 1500mg, please consult your health care provider for advice.

If any of the following happens, stop taking Genologix Omega 3 Fish Oil 1500mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Genologix Omega 3 Fish Oil 1500mg. You may need urgent medical attention or hospitalisation.

unusual bleeding or bruising, nosebleeds or bleeding gums.

Tell your doctor if you notice any of the following:

Frequency unknown:

- fishy aftertaste or burping (“fish burps”),
- bad breath,
- heartburn, indigestion or nausea (feeling sick),
- loose stools or diarrhoea.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of Genologix Omega 3 Fish Oil 1500mg.

You can also report side effects directly to Genologix by completing the side effect report form on our website at https://genologix.co.za/adr-form-page/, or by contacting us on 087 094 0594, WhatsApp 060 532 8317 or info@genologix.co.za.

5. How to store Genologix Omega 3 Fish Oil 1500mg

Store all medicines out of reach of children.

- Store in a cool, dry place at or below 25 °C.
- Protect from light, heat and moisture.
- Keep the soft capsules in the original pouch. Reseal the pouch tightly after each use.
- Do not store in a bathroom or in a hot car.
- Do not use after the expiry date printed on the pouch.
- Do not use Genologix Omega 3 Fish Oil 1500mg if the pouch seal is broken, or if the soft capsules are leaking, stuck together or smell strongly rancid.

Return all unused 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 Genologix Omega 3 Fish Oil 1500mg contains

The active substance is fish oil 36:24 TG (concentrated fish oil in triglyceride form), providing the omega-3 fatty acids EPA and DHA.

Active ingredient	Per soft capsule	Per daily dose (2 soft capsules)
Fish oil 36:24 TG [sardine (*Sardina pilchardus*) and/or anchovy (*Engraulis ringens*)]	1 250 mg	2 500 mg
providing eicosapentaenoic acid (EPA)	450 mg	900 mg
providing docosahexaenoic acid (DHA)	300 mg	600 mg
total omega-3 (EPA + DHA)	750 mg	1 500 mg
balance: other fatty acids and vitamin E oil	500 mg	1 000 mg

The other ingredients are gelatine (bovine), glycerine and vitamin E oil. Gelatine and glycerine form the soft capsule shell. Vitamin E oil is a natural antioxidant mixed into the fish oil to protect it from going off.

What Genologix Omega 3 Fish Oil 1500mg looks like and contents of the pack

Light yellow, transparent, oblong soft gelatine capsules filled with a clear, light yellow oil.

Genologix Omega 3 Fish Oil 1500mg is available in two pack sizes: 60 soft capsules (30 daily doses) and 240 soft capsules (120 daily doses). Both are packed in a resealable, laminated, light-protective pouch.

Holder of Certificate of Registration

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Registration number

Not applicable. Unregistered complementary medicine, Act 101/1965.

Access to the corresponding Professional Information

The Professional Information for Genologix Omega 3 Fish Oil 1500mg is available on request from Genologix on 087 094 0594 or info@genologix.co.za. Address your correspondence for the attention of the Responsible Pharmacist.