

# PATIENT INFORMATION LEAFLET

## SCHEDULING STATUS

[s0]

### NUTRIVIVA OH!MEGA™ – softgel capsule

Active Ingredient	Quantity per capsule	Quantity per serving
Fish Oil 36:24 TG	1250mg	2500mg
providing		
Eicosapentaenoic Acid (EPA)	450mg	900mg
Docosahexaenoic Acid (DHA)	300mg	600mg

**Sugar free**

### COMPLEMENTARY MEDICINE: Health Supplement – Combination Product

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

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

NUTRIVIVA OH!MEGA is available without a doctor's prescription, for you to maintain your health. Nevertheless, you still need to use NUTRIVIVA OH!MEGA carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NUTRIVIVA OH!MEGA 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 NUTRIVIVA OH!MEGA is and what it is used for.
2. What you need to know before you take NUTRIVIVA OH!MEGA.
3. How to take NUTRIVIVA OH!MEGA.
4. Possible side effects.
5. How to store NUTRIVIVA OH!MEGA.
6. Contents of the pack and other information.

1. **What is NUTRIVIVA OH!MEGA used for**

NUTRIVIVA OH!MEGA contains Omega-3 fatty acids, which help maintain normal cardiovascular function and contribute to the maintenance of normal brain function.

### **What you need to know before you take NUTRIVIVA OH!MEGA**

#### **Do not take NUTRIVIVA OH!MEGA**

- If you are hypersensitive (allergic) to fish oil; seafood; glycerine; Vitamin E oil or any of the other ingredients of NUTRIVIVA OH!MEGA (listed in section 6).

### **Warnings and precautions**

Take special care with NUTRIVIVA OH!MEGA:

- If you are having any surgical procedure done. You should stop taking NUTRIVIVA OH!MEGA at least two weeks before an operation.
- If you are sensitive to aspirin, EPA might affect your breathing.
- If you suffer from Irregular heartbeat (arrhythmia): EPA might increase the risk of irregular heartbeat
- An implanted device to prevent irregular heartbeat: Fish oil might increase the risk of irregular heartbeat in patients with an implanted defibrillator. Stay on the safe side and avoid fish oil supplements.
- If you have Bipolar disorder, taking fish oil might increase some of the symptoms of this condition.
- Conditions in which the immune system response is lowered (including HIV/AIDS): Higher doses of fish oil can lower the body's immune system response. This could be a problem for people whose immune system is already weak.
- Diabetes: Taking high doses of fish oil might make it more difficult to control blood sugar levels.
- Familial adenomatous polyposis: There is some concern that fish oil might further increase the risk of getting cancer in people with this condition.
- Liver disease: Fish oil might increase the risk of bleeding in people with liver scarring due to liver disease.

### **Children**

Not intended for children younger than 18 years.

### **Other medicines and NUTRIVIVA OH!MEGA**

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

Tell your doctor or pharmacist if you are currently taking:

- **Antihypertensive medicines** (used to treat high blood pressure) or supplements with a blood pressure-lowering effect. EPA and DHA might lower blood pressure. Taking fish oil along with medications that lower blood pressure might cause blood pressure to go too low. Monitor your blood pressure closely.
- **Antidiabetic drugs** (*used to control blood sugar levels in diabetes*): DHA might increase blood sugar levels. Taking DHA along with diabetes medications might reduce the effects of these medications. Monitor your blood sugar closely.
- **Anticoagulant/ anti-platelet medicines** (medications used to slow blood clotting) or supplements that influence blood clotting. Taking NUTRIVIVA OH!MEGA might slow blood clotting. Taking NUTRIVIVA OH!MEGA along with medications that also slow blood clotting might increase the risk of bruising and bleeding.
- **Birth control pills (Contraceptive drugs)**: These may reduce the effect of fish oil on lowering triglyceride levels.
- **Cyclosporine (Neoral, Sandimmune)**: Fish oil may increase the levels of cyclosporine in the body, potentially enhancing its effects and side effects.
- **Orlistat (Xenical, Alli)**: Orlistat may reduce the absorption of fish oil. To avoid this, take fish oil at least 2 hours apart from orlistat.
- **Sirolimus (Rapamune)**: Fish oil may increase the levels of sirolimus in the body, potentially enhancing its effects and side effects.
- **Tacrolimus (Prograf)**: Fish oil may increase the levels of tacrolimus, potentially enhancing its effects and side effects.

### **Pregnancy, breastfeeding and fertility**

Safety in fertility, pregnancy and lactation has not been established.

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**

NUTRIVIVA OH!MEGA should not affect the ability of individuals to drive or operate machinery. If you experience side effects which may affect these abilities, do not drive or operate machinery until the effects have completely disappeared.

### **3. How to take NUTRIVIVA OH!MEGA**

Do not share your medicines with any other person.

Always take NUTRIVIVA OH!MEGA 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: The usual dose is 2 softgel capsules daily.

Children: Not intended for children younger than 18 years.

Do not exceed the recommended dose.

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 NUTRIVIVA OH!MEGA than you should**

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

### **If you forget to take NUTRIVIVA OH!MEGA**

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

#### **4. Possible side effects**

NUTRIVIVA OH!MEGA can have side effects.

Not all side effects reported for NUTRIVIVA OH!MEGA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NUTRIVIVA OH!MEGA, please consult your health care provider for advice.

If any of the following happens, stop taking NUTRIVIVA OH!MEGA and tell your doctor immediately or go to the casualty department at your nearest hospital.

- swelling of the hands, feet, ankles, face, lips and 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 NUTRIVIVA OH!MEGA. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Diarrhoea
- Heartburn
- Skin rash
- Burping
- Nausea
- Stomach discomfort
- Fishy aftertaste or breath

Side effect with unknown frequency:

- Allergic reactions
- Increased bleeding risk (nosebleeds, bleeding gums)
- Low blood pressure (hypotension)
- Headaches
- Gastrointestinal symptoms
- Increased risk of atrial fibrillation with high doses
- heavy metal contamination

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 or nurse. 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 NUTRIVIVA OH!MEGA.

**5. How to store NUTRIVIVA OH!MEGA.**

Store all medicines out of reach of children.

Store at or below 25 °C in a dry, cool dark place.

Protect from moisture and direct light.

Store in original packaging.

**6. Contents of the pack and other information.**

What is found in NUTRIVIVA OH!MEGA

Active Ingredient	Quantity per capsule	Quantity per serving	% NRV per 2 softgels (serving size and
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			<b>maximum daily dose)</b>
Fish Oil 36:24 TG	1250mg	2500mg	*
providing			*
Eicosapentaenoic Acid (EPA)	450mg	900mg	*
Docosahexaenoic Acid (DHA)	300mg	600mg	*

The other ingredients are Gelatine (bovine) capsule, Glycerine, Vitamin E oil.

### **What NUTRIVIVA OH!MEGA looks like and contents of the pack**

Yellow/Gold soft gel capsules

60 soft gels, packed in an appropriately labelled amber glass bottle with a metal lid.

### **Holder of Certificate of Registration**

Nutriviva (Pty) Ltd

Unit 2 Nguni Business Park

1 Nguni Way

Waterfall

3610

Email: [info@nutriviva.co.za](mailto:info@nutriviva.co.za)

**Tel:** +087 094 0594

### **This leaflet was revised in**

October 2025.

### **Registration**

To be allocated by SAHPRA.