



PROFESSIONAL INFORMATION

Scheduling Status: **SO**

1. Proprietary Name

Omega-3

2. Qualitative and Quantitative Composition

Each capsule contains the composition as per table 2.1 below.

2.1 Composition

Each soft gel capsule contains	
Fish Oil (tuna and anchovy)	1000 mg
Providing EPA (Eicosapentaenoic)	360 mg
Providing DHA (Docosahexaenoic)	240 mg
Total Omega-3 Fatty Acids	650 mg

2.2 Sugar Free.

2.3 For full list of excipients see section 7.1.

3. Pharmaceutical Form

60 soft gel capsules containing yellow coloured oil.

4. Clinical Information

4.1 Indications for Use

Indicated for individuals who may have a deficiency in omega-3 fatty acids. It may assist with immune function, cardiovascular health, joint; eye; brain and skin health, and support mood regulation.

4.2 Method of Administration and Posology

4.2.1 Administration

Orally.

4.2.2 Posology

Adults and children over 18 only.

Take 1-2 soft gel capsules daily.

Take capsules with a sufficient quantity of water.

Do not chew the capsules swallow whole.

Take capsules at approximately the same time every day.

4.3 Contraindications

Not recommended for individuals who are hypersensitive (allergic) to fish or any of the ingredients contained in the product.

4.4 Special Warnings and Precautions

Not recommended for individuals who are under the age of 18.

4.5 Interactions

Fish oil: Moderate risk of interaction with antihypertensive drugs, contraceptive drugs, cyclosporine, orlistat, sirolimus and tacrolimus.



4.6 Pregnancy and Lactation

The safety in pregnancy and breastfeeding has not been established.

4.7 Effects on ability to drive and use machinery.

No known effect.

4.8 Side Effects

Generally, well tolerated. Most common adverse effects: abdominal pain, bad breath, fishy aftertaste, heartburn, increased LDL cholesterol levels, loose stools, nausea, and rash.

5 Pharmacological Classification

Category D: 34.6: Fats, Oils and Fatty Acids.

Complementary Medicine.

6 Pharmacokinetic Properties

Absorption:

EPA maximum total plasma concentration occurs after 5-6 hours after intake, while maximum total red blood cell

concentration occurs after 8-24 hours. DHA peaks six hours after intake, with rapid reduction (50% at 8 hours). DHA

status is determined by measuring plasma phospholipid and red blood cell phospholipid as well as sperm plasma.

Omega: the fatty acids are packed into chylomicrons and absorbed into the lymph before entering the circulation.

Distribution:

EPA: after about 6-12 weeks, levels of EPA in red blood cells are about 50% higher than baseline when algal oil containing EPA is consumed.

DHA levels are known to be higher in tissues such as the brain and retina.

Omega 6 fatty acids enter the circulation in chylomicrons. Enzymes in the blood remove the omega fatty acids from the triglycerides within the chylomicrons to allow uptake into various cells of the body.

Metabolism:

The mean half-life of EPA ranges between 70-89 hours.

Once omega 6 fatty acids are taken up by cells, they are metabolized by enzymes that increase their length and unsaturation.

7 Pharmaceutical Information

7.1 List of Excipients

Bovine gelatine (capsules)

7.2 Incompatibilities

None.

7.3 Shelf Life

24 months from date of manufacture.

7.4 Storage

Store in a cool dry place, between 15°C -25°C. Store in original container.

7.5 Presentation

60 yellow soft gel capsules packed in a 300 ml cylindrical white container with a lid and packaged.

7.6 Disposal and handling of product

All unused medication should be disposed of in accordance with local regulatory authority.



FOODGROWN™©

Version 1.0

May 2023

8. Holder of certificate of registration

FoodGrown™©

371 Angus Crescent

Northlands Business Park

North Riding

Gauteng

South Africa

9. Registration Number

Still to be allocated

10. Date of first authorisation

Still to be allocated

11. Date of review

New

12. Reference: <https://naturalmedicines.therapeuticresearch.com/>

APPLICANT DETAILS:

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