designs for health® Australia

OmegAvail™ 1250

High strength ultra-pure omega-3 fish oil

Soft Capsule

OVERVIEW

- Concentrated source of premium fish oil
- Superior fish oil oxidation parameters*
- Sourced from sustainably caught wild sardine and anchovy
- Zero carbon footprint product
- Non-GMO

*Compared to all internationally recognised quality specifications.

No Added Gluten

No Added Dairy

No Added Nuts

No Added Lactose

Active Ingredients (per soft capsule)	
Concentrated fish omega-3 triglycerides	1.25 g
Equiv. to eicosapentaenoic acid (EPA)	750 mg
Equiv. docosahexaenoic acid (DHA)	250 mg

Directions for Use

Adults: Take 1 to 2 capsules per day, or as directed by your healthcare professional.

Allergen Information

No Added: gluten, dairy, lactose or nuts.
Contains: fish, sulphites and phenylalanine.

Pack Size	120
Serving per pack	60–120 serves

Excipients

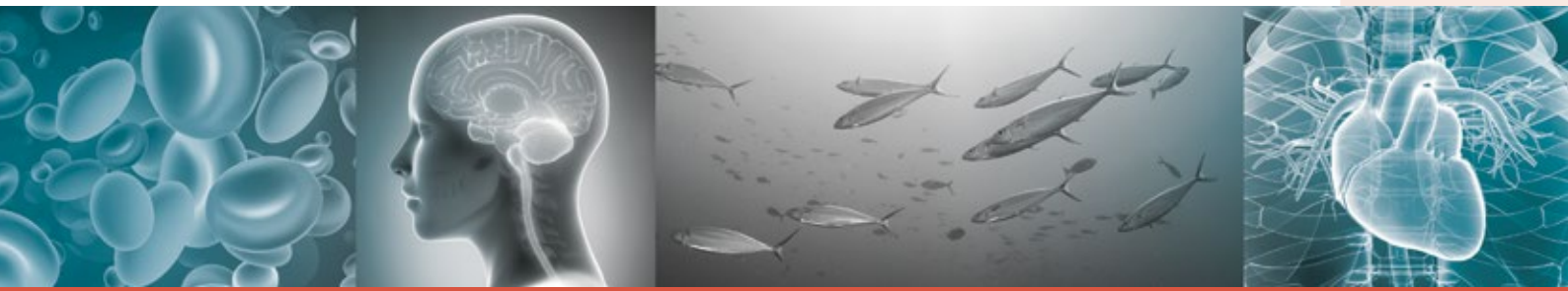
Gelatin
Glycerol
Annatto
Bixa orellana (Annatto) seed
Natural lemon oil
Purified water

Prescribing Information:

Caution advised in individuals with bleeding disorders – use under professional supervision.[1]

Theoretically, concomitant use with antiplatelet and anticoagulant medications may increase risk of bleeding. Caution advised.[1]

Designed, encapsulated and packed in Australia from local and imported ingredients.



EDUCATION

Concentrated fish omega-3 triglycerides (Fish oils) contain eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). EPA and DHA are long-chain polyunsaturated essential fatty acids with a wealth of research regarding their impacts on overall health, as well as targeted therapeutic benefits.

Polyunsaturated fatty acids are comprised of two groups of essential fatty acids, omega-6's (linoleic acid) and omega-3's (alpha-linoleic acid), with the latter subsequently converting to eicosapentaenoic (EPA) and docosahexaenoic acid (DHA).[16,17,18] They are classified as essential because the rate of EPA and DHA biosynthesis from ALA is very low (8% and 1% respectively), consequently maintaining optimal endogenous levels to effectively support physiological functional processes requires regular intake from dietary sources. However, a broad body of evidence confirms that in many Western countries, intake of EPA and DHA across many sub-population groups is inadequate. This is a consequence of both inadequate omega-3 intake and excessive omega-6 consumption[17,18] EPA and DHA are also classified as essential because of the many important physiological functions they are involved in, including supporting heart health, brain and cardiovascular function.[17,18]

Pharmacokinetics

Omega-3 polyunsaturated fatty acids (n-3 PUFA) are hydrolysed in the intestines to monoglycerides and free fatty acids. These by-products form part of micelles that are then absorbed via passive diffusion into the enterocytes.[1,2]

Free fatty acids are then involved in chylomicron formation. Chylomicrons enter the circulation and are distributed throughout tissue to be metabolised or stored.[1,2]

Metabolism of n-3 PUFAs can take place via a number of processes, including beta-oxidation, enzymatic biotransformation, as well as the production of lipid mediators.[3]

N-3 PUFAs are then incorporated into the phospholipid cell membrane where, upon stimulation, are released and converted to 20-carbon eicosanoids such as prostaglandins, prostacyclins and thromboxanes which go on to have some very influential biological effects in the immune and cardiovascular systems. N-3 PUFAs stored in this way in the brain contribute to the structure of the neuronal membrane and the myeline sheath. When not stored in cell membranes, dietary fats are stored in fatty tissues until they are oxidised and enter the Kreb's cycle.[16]

Mechanisms of action

Inflammation

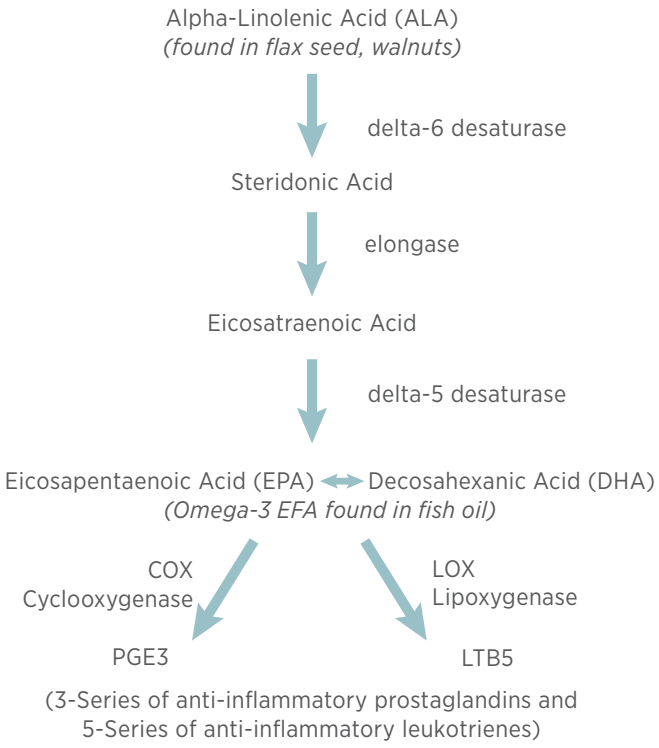
EPA and DHA are responsible for the partial inhibition of multiple inflammatory processes, including the production of prostaglandins, leukotrienes and pro-inflammatory cytokines. EPA and DHA compete with arachidonic acid for the enzymes involved in the production of pro-inflammatory mediators, inhibiting the inflammatory cascade.[4]

Cyclo-oxygenase-2 (COX-2) is responsible for the stimulation of prostaglandins at inflammatory sites. DHA specifically reduces COX-2 expression and activity, resulting in reduced inflammation.[5]

Part of the anti-inflammatory action of EPA and DHA is due to its ability to inactivate pro-inflammatory transcription factor nuclear factor-kB. This action in turn reduces the expression of pro-inflammatory genes, as well as the activation of anti-inflammatory transcription factor peroxisome proliferator-activated receptor-gamma.[6]

N-3 PUFAs have the same effect as antioxidants by these same anti-inflammatory mechanisms, helping to prevent damage to endothelial cells and even cell death.[7]

OMEGA-3 FATTY ACID PATHWAY



Eye Health

DHA is shown to have an integral role in maintaining the structure and function of the retina. DHA is a major structural element of the outer membrane of the retinal photoreceptor.[9]

High PUFA intake is shown to improve the response of the retinal cells to oxidative and inflammatory damage in animal studies.[10]

Nervous System

EPA and DHA are useful in supporting nervous system health and function via maintaining the nerve cell membranes. DHA is the most prevalent PUFA in the central nervous system and is required during brain and central nervous system development.[11] Research has shown that a reduction in DHA can result in a reduced capacity to process sensory input.[12]

There is growing evidence that n-3 PUFAs protect against demyelination through their anti-inflammatory actions, including inhibition of microglia activation by inflammatory cytokines such as interferon-gamma (IFN-γ).[13]

Cardiovascular System

A significant body of evidence has demonstrated an association between endogenous levels of EPA and DHA and cardiovascular health, which is attributed to a significant number of cardioprotective mechanisms.[19] Such mechanisms include antioxidant, antiplatelet, promoting healthy blood lipid levels, cell membrane and vascular endothelial function, as well as reducing pro-inflammatory mediator concentrations (eicosanoids, prostaglandins, leukotrienes, and resolvins).[19-22]

This has translated into clinically relevant outcomes, with findings from a broad body of evidence demonstrating a dose-dependent beneficial effect of omega-3 supplementation for improving cardiovascular health as measured by several clinical and biological endpoint subtypes.[21-24]

N-3 PUFAs can reduce endothelial dysfunction and arterial stiffness. Oxidative stress can induce endothelial dysfunction by reducing nitric oxide bioavailability – NO is essential for healthy vasodilation and has an anti-atherosclerotic action.[7]

It is thought that the positive effect of n-3 PUFAs on blood lipids is due to their ability to inhibit the production of very low-density lipoprotein (vLDL) in the liver.[14]

Cognitive Function

DHA is highly prevalent in the brain. It is estimated that 20% of the dry weight of the brain is comprised of PUFAs.[11] Optimal levels are necessary for normal brain, structure, function and health at all life stages.[17,18] Specific mechanisms of omega-3 fatty acids that are involved in supporting healthy brain function include being a key cell membrane component thus promoting optimal membrane fluidity, neurogenesis, intracellular signalling, synaptic transmission and repair processes, as well as inhibiting pro-inflammatory mediator-driven neuroinflammation.[17]

Omega-3 enhances neurotransmitter signalling and binding in the brain by improving membrane fluidity in the lipid bilayer.[11] Furthermore, low DHA intake may impact neurotransmitter production in the brain, including acetylcholine, dopamine, serotonin, glutamate, norepinephrine and gamma-aminobutyric acid (GABA).[11]

Clinical evidence demonstrates a beneficial effect of omega-3 supplementation in young and middle-aged adults and older individuals.[15,17] A comprehensive systematic review found that in young adults, omega-3 supplementation improved endogenous fatty acid profiles, reading abilities (phonologic decoding time and visual analysis time) and also enhanced neurocognitive function.[17] Whilst other research into healthy ageing subjects notes that n-3 PUFAs may even help to slow cognitive decline.[15] Improvements observed in middle-aged adults included enhanced memory functionality and brain structure (white matter microstructural integrity and grey matter volume), while in older individual's, omega-3 supplements protected against neurodegeneration.[17]

Animal studies have shown that diets rich in n-3 PUFAs also maintain the integrity of the blood-brain barrier, which is associated with better cognitive function.[15]

Vivo Mega

Two vital factors to consider when ingesting therapeutic quantities of omega-3 fatty acids is purity and environmental impact. Extracted using urea technology, OmegAvail™ 1250 has superior oxidation parameters. It also has exceptional environmental parameters, being sustainably certified by IFFO Global Standard for Responsible for Supply and Friend of the Sea.

SUSTAINABLE AND RESPONSIBLE

- > Target stock not overexploited
- > Fishery to generate maximum 8% discarded waste
- > No by catch of endangered species
- > No impact to the seabed
- > Gradual reduction of carbon footprint

EDUCATION (Continued)

SUPERIOR PERFORMANCE AGAINST ALL INTERNATIONALLY RECOGNISED QUALITY SPECIFICATIONS

	VivoMega 6020 TG Premium Specifications (max)	Best in Class	IFOS 5 Star Criteria	GOED Monograph	EU legislation/ Ph Eur
OXIDATION PARAMETERS					
Peroxide value (meq/kg)	2	✔	5	5	10
Anisidine value	8*	✔	20	20	30
Totox	10*	✔	19.5	26	N/A
Acid Value (mg KOH/g)	1	✔	3.0	N/A	3.0
ENVIRONMENTAL PARAMETERS					
Arsenic (mg/kg)	0.1	NEUTRAL	0.1	0.1	N/A
Cadmium (mg/kg)	0.002	✔	0.1	0.1	1
Mercury (mg/kg)	0.002	✔	0.1	0.1	0.1
Lead (mg/kg)	0.003	✔	0.1	0.05	0.1
PCBs (209 Congeners) (mg/kg)	0.005	✔	0.045	0.09	0.2
Dioxins+Furans (PCDD+PCDF) (pg/g)	1	NEUTRAL	1	1.75	1.75
Dioxins-like PCBs (pg/g)	0.5	✔	1.5	3	N/A
Dioxins+Furans+Dioxin-like PCBs (pg/g)	1.5	✔	N/A	3	6
Sum PAH4 (ng/g)	2	✔	N/A	N/A	10
Benzo(a)pyrene (ng/g)	1	✔	N/A	N/A	2
Pesticides (mg/kg)	0.01	✔	N/A	N/A	N/A

*Platinum products has a standard specification maximum for Anisidine value of 10 and Totox 12, awaiting stability studies results.

Designs for Health Quality Guarantee

Designs for Health medicines that are listed on the Australian Register of Therapeutic Goods will display an AUSTL number on the label. Listed medicines in Australia need to be manufactured according to legislated standards set out in Therapeutic Goods Order 101. TGO101 legislation sets out minimum quality standards for medicines supplied in Australia that display an AUSTL number. It mandates testing for:

- Impurities such as heavy metals (including lead, mercury, cadmium and arsenic), pesticides and residual solvents
- Dissolution (to ensure the capsule will dissolve once taken)
- Uniformity (to ensure that every capsule is the same)

Final assay testing is also performed to ensure that what we have on the label is in each capsule, and microbiological testing is performed to ensure that no microbial contamination has occurred during the encapsulation and packing process.

EDUCATION (Continued)

MANUFACTURING PROCESS FOR VIVOMEGA CONCENTRATED TG PLATINUM (>80% EPA/DHA)