

# Omega-3 Women's Formula Softgels



## Product Summary:

Supplies the ideal balanced blend of omega oils to support women's unique nutritional needs. Supports circulation and cardiovascular health, and balances the essential fatty acid profile.

## Properties/Uses:

The claim as approved by the *Natural Health Product Directorate* (NHPD): Source of essential fatty acids, including alpha-linolenic acid (omega-3) for the maintenance of good health for women. Supports cardiovascular health.



CARDIOVASCULAR



## Pharmacology:

The principal reason people supplement with fish oil is to increase the intake of ready made omega-3 EPA (eicosapentaenoic acid) and DHA (eicosahexaenoic acid), by-passing their natural endogenous production from alpha-linolenic acid.

However, deriving the optimal amount of EPA and DHA from dietary alpha-linolenic acid could become circumstantially challenged, leaving the possibility that the available EPA and DHA may not be adequate to optimally meet the physiological needs of the body. This certainly becomes a concern in an older person for failing age-related metabolic reasons. As well though, in any person the happenstance dietary ratio of the two essential fatty acids, linoleic acid and alpha-linolenic acid, is a major life-style factor mediating the formation rates of EPA and DHA from alpha-linolenic acid. Consuming too much omega-6 linoleic acid relative to omega-3 alpha-linolenic acid causes a diminished formation of EPA and DHA. A shortfall in EPA and DHA can occur because the same biotransformation enzymes serve both omega families, thus an exaggerated presence of omega-6 substrate blunts by way of competitive inhibition the omega-3 biotransformations.

The optimal dietary ratio between the essential fatty acids is thought to be 4:2 to 4:1, in favour of omega-6.<sup>8,10</sup> Omega-6 linoleic acid is supplied in all of the common polyunsaturated and monounsaturated oils consumed in North America, while omega-3 linolenic acid is supplied only in soy, canola, and flaxseed oils, as well as in walnuts. Unfortunately, the dietary ratio of the two essential fatty acids for most North Americans is closer to 14 to 20 parts of omega-6 linoleic acid, to 1 part of omega-3 linolenic acid.<sup>8,9</sup> This unhealthy ratio range is due in part to high temperature destruction of alpha-linolenic acid when soy oil and canola oil are refined. Flaxseed oil products do not receive commercial refinement, so remain an excellent source of alpha-linolenic acid. A second reason for a dietary ratio imbalance is that most polyunsaturated and monounsaturated oils consumed in North America do not contain omega-3 linolenic acid as a constituent.<sup>8</sup>

This dietary pattern of 14-20 parts of omega-6 linoleic acid to 1 part of omega-3 alpha-linolenic acid is recognized to be a major contributing factor in the leading health problems that plague North America.<sup>8,9</sup> Dietary fatty acids are incorporated into cell membrane phospholipids as structural elements.

The ratio of the dietary essential fatty acids is structurally reflected in cell membranes as a distribution of omega-6 and omega-3 fatty acid derivatives.

When omega-6 linoleic acid is consistently consumed in excess relative to omega-3 linolenic acid, then so called "bad" Series 2 prostaglandins, leukotrienes, and thromboxanes are over expressed, leading to health problems. Prime examples of Series 2 eicosanoid over expression are pro-thrombosis states and pro-inflammatory states. Leading causes of death and life altering disabilities in North America relate to coronary thrombosis, cerebral thrombosis, and pulmonary embolism. Furthermore, a growing body of evidence implicates generalized inflammation as a major player in a number of health problems including risk for heart attack and Alzheimer Disease.<sup>11,12</sup>

Supplemented EPA is able over time to adjust an omega-6 to omega-3 imbalance in membrane fatty acids eicosanoid precursors.<sup>8,9</sup>





DHA is very important to the brain, retina, testes, and adrenal glands for facilitating optimal functioning. Inadequate DHA in the brain is thought to be an important contributing factor in many neurological functional problems. Intriguing brain research has drawn a possible connection between DHA and arachidonic acid (AA) and some of the more difficult childhood learning and behavioral problems seen in the early pre-school or elementary school years, and even in early adolescence. These problems include dyslexia, attention deficit disorder (ADD), and attention deficit hyperactivity disorder (ADHD). They are associated with learning, psychological, and social disruptions in the normal life quality and development of a child or young person, with possible life long repercussions. Parents and teachers are challenged to provide effective learning and to shape appropriate behavior. This brain research is pointing to new nutritional ways to address these difficult learning and behavioral problems with neurologically active DHA and omega-6 gamma-linolenic acid (GLA) and arachidonic acid (AA).

Researchers have found that the fatty acids DHA and AA are highly concentrated in the synaptic membranes, the juncture where neurons exchange and process information, where learning and behavior are forged<sup>2</sup>. Researcher Laura J. Stevens, PhD, and her fellow scientists at Purdue University have shown that DHA levels in the blood of 53 boys suffering from ADHD was significantly lower than DHA levels found in 43 matched boys without ADHD. This has been interpreted to mean that ADHD sufferers may not make DHA well enough to facilitate the optimal construction of the synaptic membranes, thereby impairing the brain's management of childhood control over responses to environmental stimuli, leading to hyperactivity, inattentive, and impulsive behavior. The researchers concluded that supplementing with DHA and arachidonic acid may be useful in treating or managing ADHD.





## Manufactured product information:

**Manufacturer:**

WN Pharmaceuticals® Ltd.

**Size/UPC:**

90's ..... 7 77747 10304 1

**NPN:**

80013010

**Expiry Date:**

36 months from date of manufacture.

**Active Ingredients:**

Each softgel contains:

Fish Oil Concentrate (anchovy, sardine and/or mackerel).....	535 mg
Omega-3 Fatty Acids .....	320 mg
EPA (Eicosapentaenoic Acid).....	200 mg
DHA (Docosahexaenoic Acid) .....	100 mg
Evening Primrose Oil (Oenothera biennis) (seed).....	250 mg
GLA (Gamma-Linolenic Acid) .....	25 mg
Organic Flaxseed Oil (Linum usitatissimum) (seed).....	250 mg
ALA (Alpha-Linolenic Acid).....	130 mg

**Non-Medicinal Ingredients (in descending order):**

Softgel capsule (gelatin, glycerin, purified water), vitamin E.

**Appearance:**

Clear yellowish oil encapsulated in a size 22 oblong clear soft gelatin shell

**Packaging:**

300 cc white round bottle with safety seal under a 45 mm white induction sealed cap with vented interior seal and a label applied to the bottle. Lot number and expiry date are printed on label applied to exterior of bottle.

**Storage:**

Store in a cool, dry place at a temperature 15 – 25°C. Protect from light.





## Dose:

The NHPD Monograph for Fish Oil indicates that health claims can be attributed to products containing between 100 and 3000 mg of EPA + DHA per day. The NHPD Monographs for Evening Primrose Oil and Flax Oil indicate dosages of 2 g per day have medicinal qualities. A combination rationale of the 3 products indicates medicinal quantities are present.

It is recognized that the human body requires a large variety of nutritional substances necessary for optimal growth and development. Among these crucial elements, Omega-3 fatty acids are termed 'essential' because they are necessary for good health. Since the human body cannot make them on its own, Omega-3 essential fatty acids must be supplied in the diet.

As recommended by the Natural Medicines Comprehensive Database: 1- 4 grams per day.<sup>15</sup>

## Directions:

**(Adults):** 2 softgels, 1 – 3 times daily or as recommended by a physician.

## Caution:

The caution as approved by the *Natural Health Product Directorate* (NHPD): KEEP OUT OF THE REACH OF CHILDREN. Consult a physician prior to use if you are taking blood thinners. STORE AT ROOM TEMPERATURE IN A DARK, DRY PLACE. DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

Ocean fish oils may predispose a person to post-surgical bleeding problems.

However, Vanschoonbeek *et al* note that various papers explicitly mention the absence of easy bruising or clinical signs of postoperative bleeding after fish oil intake by patients with cardiovascular disease.<sup>1-4</sup> Nevertheless, until a formal statement by a surgical expert body approves fish oil use up to hospital admission, it seems prudent to recommend that fish oil supplements be discontinued at least one week before surgery, and resumed upon the recommendations of the patient's physician.

## Deficiency Symptoms:

A deficiency in omega-3 can lead to host of health issues including cardiac and circulatory disorders, disorders of the skin (eczema), disorders of the kidneys and liver, with various inflammatory problems, arthritis, weight disorder and failure of the immune system.



## Drug Interactions/Contraindications:

The effect of fish oils on anticoagulant therapy has been uncertain. Positive interactions between omega-3 polyunsaturated fatty acid intake and oral anticoagulants have been noted, without clinically relevant bleeding problems.<sup>1,5</sup>

However, fish oil (EPA) can increase the prothrombin time (PT) in certain people on warfarin. One case was reported in 2004 in which the PT went from 2.8 to 4.3 within one month after the patient increased their fish oil intake from 1 gram per day to 2 grams.<sup>6</sup>

This reported effect of ocean fish oil on the prothrombin time in conjunction with warfarin is not consistent with other observations. Bender et al found that fish oil supplementation in doses of 3-6 grams per day does not seem to create a statistically significant affect on the anticoagulation status of patients receiving chronic warfarin.<sup>7</sup> Making changes in the pattern of supplemental fish oil intake after the establishment of an anticoagulant dosage may be a risk factor for loss of coagulation control.

Eicosapentaenoic acid (EPA) in a high dose range may present an additive effect with other natural products known to be blood thinners. Other common mild natural blood thinners include garlic, MSM, grape seed extract, cayenne, Ginkgo biloba, and perhaps vitamin E >400 IUs. Those taking fish oils should also be supplementing with natural vitamin E at 200 IUs to 400 IUs to protect against fatty acid peroxidation.

Initiating fish oil supplements after being stabilized on anticoagulant therapy is contraindicated unless supervised by a physician.

Supplementation of fish oil is contraindicated for at least one week before surgery.

Supplementation of fish oil is contraindicated in those who have hemophilia.

Ocean fish oils may predispose a person to post-surgical bleeding problems. It is prudent to recommend that fish oil supplements be discontinued at least one week before surgery, and resumed upon the recommendations of the patient's physician.



*Antihypertensive drugs:* Fish oils can lower blood pressure and might have additive effects in patients taking antihypertensive.

*Contraceptive drugs:* There is some evidence that contraceptive drugs might interfere with the triglyceride lowering effects of fish oils.

*Vitamin E:* Fish oils can reduce vitamin E levels.

*Bipolar disorder and depression:* Symptoms of hypomania can develop in patients taking fish oils who have bipolar or major depressive disorders.

*Cirrhosis:* Theoretically, fish oils may lower mean arterial pressure and may increase risk of bleeding.

*Diabetes:* in doses greater than 3 grams per day, fish oil can increase blood glucose levels. However, lower doses do not affect blood glucose.

*Hypertension:* Fish oil can lower blood pressure.

*Immunodeficiency:* Higher doses of fish oils might cause suppression of immune and inflammatory responses.





## Allergen Content/Ingredient Sensitivity:

NO	YES
Artificial Colors	Fish
Artificial Flavors	Sulphites (<10 ppm)
Artificial Sweeteners	
Corn Products	
Egg Products	
Gluten	
Hydrolyzed Plant Protein	
Lecithin	
Milk Products	
Peanuts	
Preservatives	
Sesame Products	
Soy Products	
Starch/Modified Starch	
Tartrazine	
Tree Nuts	
Wheat Products	
Yeast	

### NOT ACCEPTABLE FOR THE FOLLOWING DIETARY RESTRICTIONS:

Free of animal products

Kosher







## References:

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8. Simopoulos, Artemis P., Robinson, Jo, *The Omega Plan*, HarperCollins Publishers, New York, 1998
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11. Tomiyama, H., *et al*, Elevated C-reactive protein: a common marker for atherosclerotic cardiovascular risk and subclinical stages of pulmonary dysfunction and osteopenia in a healthy population, *Atherosclerosis*, Jan, 178(1):187-92, 2005
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15. Natural Medicine's Comprehensive Database. Fish Oil [internet]. 2005 [cited August 23, 2005]. Available at: [www.naturaldatabase.com](http://www.naturaldatabase.com)

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