

Lutein Complex Formula Capsules



Product Summary:

Lutein Complex formula is a herbal dietary supplement that can be used daily to support general eye health enhancement, due to the lutein content. Lutein, and its naturally occurring stereoisomer zeaxanthin, is used as part of a general carotenoid defense against oxidative stress, whether solar or metabolic. Lutein is observed to lower the risk of cataracts and age-related macular degeneration (AMD).

Properties/Uses:

The claim as approved by the *Natural Health Product Directorate* (NHPD): Helps to support eye health in conditions associated with sunlight damage, such as cataracts and age-related macular degeneration. Helps to reduce the risk of developing cataracts. Helps to improve macular pigment optical density.



EYE





Pharmacology:


Lutein Complex formula is a herbal dietary supplement that can be used daily to support general eye health enhancement, due to the lutein content. Lutein, and its naturally occurring stereoisomer zeaxanthin, is used as part of a general carotenoid defense against oxidative stress, whether solar or metabolic. Lutein is observed to lower the risk of cataracts and age-related macular degeneration (AMD).

Age-related macular degeneration is the leading cause of irreversible vision loss and legal blindness in people over 65 in North America. Vision loss in the elderly years imposes an enormous forfeiture in life quality and independence, as well as greater use of health care resources. It has been estimated that in the United States as many as 13 million people age 40 and older have signs of age-related macular degeneration, and that the disease causes visual impairment in 1.2 million. About 30 percent of those over the age of 75 have AMD, and AMD will develop in 23 percent of the remainder in 5 years.¹ In Canada, as many as 20,000 people a year are diagnosed with the more severe or “wet” form of AMD, and the Canadian National Institute for the Blind registers almost 50,000 people as legally blind as a result of AMD. This number is estimated to double by the year 2021.² Even though AMD is observed to rise sharply with age, it is not strictly a disease of the elderly.¹ At present, there are no effective medical treatments for most patients with the disease.¹

Several dietary components have been proposed and studied with regard to their ability to protect against AMD. These include antioxidant vitamins and the carotenoids, lutein and zeaxanthin. Consumption of dark green, leafy vegetables has been shown in clinical studies to reduce the risk for AMD. Structural and clinical studies have shown that these carotenoids are concentrated in the macular pigment and that such accumulation is dependent on dietary intake. Studies have also shown that the density of the macular pigment is related to preservation of visual sensitivity and possibly prevention of AMD.^{1,3} A landmark Harvard epidemiology study has shown that the risk for further progression of advanced AMD can be reduced in a linear way in proportion to the dietary lutein intake.⁴

In LAST (The Lutein Antioxidant Supplementation Trial), patients with AMD were given either 10mg of lutein, 10mg of lutein with antioxidants/vitamins/minerals or placebo. Improvements were seen in both groups given lutein, with an increased in mean eye macular pigment optical density, improved Snellen equivalent visual acuity and contrast sensitivity. Patients in the placebo group had no significant changes in any of the measured findings.⁵ Similarly, the TOZAL (Taurine, Omega-3 Fatty Acids, Zinc, Antioxidant, Lutein) study, showed supplementation for 6 months improved visual acuity in dry AMD, but recognized that treatment may be required for longer periods of time in order to improvements in other parameters, such as contrast sensitivity.⁶

In LAST II⁷, subjects were randomly assigned to 1 of 3 groups for 12 months: group 1 received 10 mg lutein per day; subjects in group 2 received 10 mg lutein per day plus a broad spectrum of antioxidants in a preparation including vitamins, minerals, amino acids, and bioflavonoids; subjects in group 3 received a maltodextrin placebo. The researchers were able to conclude once again that intervention by dietary supplementation with lutein, either alone or in combination with other vitamins and minerals and antioxidants, results in continuous increase in macular pigment optical density over the course of an entire year. In addition, other significant implications were noted:





Those individuals in greatest need of supplementation, having the lowest levels of measured macular pigment optical density, comprise the population with the greatest increase in MPOD.

Macular pigment had not yet reached a plateau for the responding groups within a year, so the level of lutein might be expected to continue to increase for some period of time beyond 1 year, and therefore continued higher dose supplementation may be beneficial for the full duration.

Bioavailability of lutein may in some part be influenced by the nutrients accompanying it at the time of ingestion.

Observational studies have also demonstrated the relationship between dietary levels of antioxidants and risk of AMD. The Age-Related Eye Disease Study (2007) examined 4,519 people and found a high dietary intake of lutein and zeaxanthin was independently associated with decreased likelihood of having neovascular AMD, geographic atrophy, and large and extensive drusen. Similarly, the Blue Mountain Eyes Study (2007) observed 2454 participants and determined that subjects in the highest quartile of dietary intake of lutein and zeaxanthin had a reduced risk of neovascular AMD, whereas those with above median intakes of these carotenoids in the diet had a reduced risk of indistinct soft or reticular drusen. In addition, a protective influence of dietary zinc against AMD was observed.⁸

The macula is a small circular region on the retina with a 4 to 5 mm radius, controlling central vision. The degeneration of the macula leads to central vision blindness, with peripheral vision remaining. Lutein, Zeaxanthin, and meso-Zeaxanthin are the only carotenoids concentrated in the macular region, while beta-carotene is virtually absent from the macula. Lutein is the more prevalent of the two in nature and therefore in the diet, and its concentration in the plasma usually exceeds that of zeaxanthin by approximately 3:1.8 However, in the retina the concentration of zeaxanthin and another stereoisomer, mesozeaxanthin, in combination exceed the concentration of lutein by approximately 2:1.8 Mesozeaxanthin is not found in the blood, and there is evidence that a chemical process in the retina converts lutein to mesozeaxanthin.³

Lutein and zeaxanthin filter blue light, which is the most damaging wavelength on macular photoreceptor structural and functional integrity. Thus, despite the body's own ability to counter blue-light induced oxidative stress and the metabolic oxidative stress of vision physiology, and despite the benefits of dietary antioxidant help in the eye, blue light must be filtered to avoid an overwhelming condition of oxidative deterioration of the macular tissue.

This product is designed for those who are unable or unwilling to ensure adequate daily dietary lutein and zeaxanthin, and for those who are already experiencing macular degeneration and want precise carotenoid remedy to arrest or at least slow its progression. When using lutein/zeaxanthin as a treatment to arrest AMD, it is recommended that the consumer consider at least 6 mg BID and preferably consider 6 mg TID and be followed by their eye professional to evaluate the efficacy of this dosage range, with adjustments as per the specialist's recommendations.

Excellent dietary sources of lutein and zeaxanthin include egg yolks, cooked collard greens, steamed spinach, kale, other dark green leafy vegetables and corn.





Grape seed extract:

Grape seed extract contains proanthocyanidins (also referred to as procyanidins, OPCs, and PCOs), one of the most beneficial groups of plant flavonoids. The antioxidant action of PCOs is approximately 50 times greater than that of vitamins C and E. One of the most advantageous features of PCOs is that they protect against both water- and fat-soluble free radicals, providing incredible protection to the cells.^{9,10}

Ginkgo biloba leaf extract:

Ginkgo biloba, a plant, has a long history of use. Its antioxidant properties, improves blood circulation by dilating blood vessels, and reduces the stickiness of blood platelets. In regards to eye health, preliminary research show benefits for macular degeneration. Ginkgo is also beneficial for supporting cognitive function and intermittent claudication and anxiety.¹¹

Bilberry extract:

Bilberry extract is widely used in Europe to treat artery, vein and capillary disorders. It seems to increase the resistance of blood capillaries and reduces their permeability and fragility. Bilberry's anthocyanosides may slow the oxidation of low density lipoproteins.¹²

Green tea extract:

The beneficial compounds of green tea are due to its high content of polyphenols. Green tea polyphenols are potent antioxidant compounds and increase the activity of antioxidant enzymes in the small intestine, liver, and lungs. The ability of green tea extract to protect against oxidative damage to LDL-cholesterol indicates that it may protect against atherosclerosis and heart disease. Studies have demonstrated that green tea polyphenols inhibit cancer.^{9,13}



Manufactured product information:

Manufacturer:

WN Pharmaceuticals® Ltd.

Size/UPC:

30's 7 77747 10290 7

NPN:

80036628

Expiry Date:

36 months from date of manufacture

Active Ingredients:

Each capsule contains:

Lutein (*Tagetes erecta*) (oleoresin from flower) 10 mg

Zeaxanthin (*Tagetes erecta*) (oleoresin from flower)..... 1.77 mg

Grape Seed Extract (*Vitis vinifera*) (seed) (80% oligomeric proanthocyanidins)..... 25 mg

Ginkgo Extract (*Ginkgo biloba*) (leaf) (24% ginkgo flavone glycosides, 6% terpene lactones)..... 40 mg

Bilberry 5:1 Extract* (*Vaccinium myrtillus*) (fruit)..... 20 mg
*Equivalent to 100 mg dried herb

Green tea extract (*Camellia sinensis*) (leaf) (40% polyphenols, 15% caffeine)..... 3 mg

Non-Medicinal Ingredients (in descending order):

Microcrystalline cellulose, gelatin capsule (gelatin, purified water), dextrin, magnesium stearate, silica

Appearance:

Brown powder with speckles in a hard gelatin capsule.

Packaging:

175 cc white round bottle with safety seal under a 38 mm white induction 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 tightly sealed container in a cool, dry place.





Dose:

In The Lutein Antioxidant Supplementation Trial II (2007), researchers were able to conclude that intervention by dietary supplementation with lutein, either alone or in combination with other vitamins and minerals and antioxidants, results in continuous increase in macular pigment optical density over the course of an entire year. In addition, those individuals in greatest need of supplementation, having the lowest levels of measured macular pigment optical density, comprise the population with the greatest increase in MPOD.⁷

Lutein supplements 10 mg/day have been safely used for a year.⁵

Directions:

(Adults): 1 capsule daily with a meal or as recommended by a physician. Consult a physician for use beyond 3 months.

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 pregnant or breastfeeding, if you have an iron deficiency, a liver disorder or develop symptoms of liver trouble (such as abdominal pain, dark urine or jaundice), or if you are taking medications for diabetes, high blood pressure, or seizures. Do not use if you are allergic to plants of the Asteraceae/Compositae/Daisy family or if you are taking health products that affect blood coagulation (e.g., blood thinners, clotting factor replacements, acetylsalicylic acid, ibuprofen, fish oils, vitamin E) as these products may increase the risk of spontaneous bleeding. STORE AT ROOM TEMPERATURE IN A DARK, DRY PLACE. DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

Deficiency Symptoms:

Lutein and zeaxanthin

There are no deficiency symptoms or direct cause of disease associated with low dietary intake of carotenoids, lutein and zeaxanthin. However, with mounting research showing correlation between lutein and zeaxanthin concentrations in the macula, and higher dietary intake of lutein rich foods help reduce the risk of macular degeneration and cataracts; lutein might soon be confirmed to be an important nutrient factor in ocular health.



Drug Interactions/Contraindications:

None known.

The following notes about beta-carotene may be important to lutein and zeaxanthin supplementation. Beta-carotene has fallen into disrepute in recent years due to the unexpected increase of lung cancer in two clinical trials using beta-carotene.¹⁴ In one trial of 29,133 Finnish men, the subjects were characterized by being smokers and consumers of alcohol. The treated subjects received 20 mg per day of beta-carotene. There was an 18 percent increase in lung cancer for the beta-carotene treated group compared to the untreated group.

In the second trial, called the Carotene and Retinol Efficacy Trial (CARET), 18,000 U.S. men and women smokers and asbestos workers were given beta carotene at the rate of 30 milligrams (50,000 IU) per day. After four years of beta-carotene intervention, there was a 28 percent increase in the rate of lung cancer over placebo, and a 17 percent increase in mortality compared to the placebo group.^{15,16,17}

Given the strong protective anticancer effect of dietary beta-carotene in the epidemiology record, one must consider that these outcomes are not typical of dietary beta-carotene. Beta-carotene given to primates in isolation to ameliorate the damage of alcohol seems to be subject itself to oxidative damage, and subsequent liver damage occurs.¹⁵ Overall, it is difficult to know what is happening in this unusual "black box" scenario. Beta-carotene may require a network of other antioxidants that preempt it from forming possible toxic by-products.

In the Finnish study cited above, those subjects who also received vitamin E with their beta-carotene did not show an increase in lung cancer.¹⁵ The data might be suggesting that the protection associated with dietary beta-carotene is likely to be realized in beta-carotene supplements only when it is complemented with other antioxidant nutrients, thus approximating nature's network of antioxidation.^{15,18} Special cases of predisposition towards cancer, as in smokers and asbestos workers, may actually serve to enlighten us of the unseen hazard of using high doses of some antioxidants without a complementary network balance. This concept has also been invoked when high amounts of vitamin C were shown to be pro-oxidants unless modulated by vitamin E.¹⁹

Based on the negative interaction of supplemented beta-carotene in appearing to accelerate lung cancer in those who consume alcohol and/or smoke, and in those who have worked in asbestos mining, it may be possible for lutein and zeaxanthin (dihydroxy-beta-carotene) to have similar adverse effects. Smokers, drinkers (uncertain as to how much alcohol is required to produce a negative effect with beta-carotene), and asbestos workers may be better advised to obtain lutein and zeaxanthin from their diet.

Long-term supplementation with beta-carotene of 15 to 60 mg per day lowers blood levels of vitamin E significantly.²⁰ Those with active macular degeneration may want to use up to 18 mgs per day of supplemented lutein. The effect of lutein and zeaxanthin on blood levels of vitamin E is not known. Accordingly, vitamin E supplementation should be practiced to be safe. Furthermore, optimal amounts of vitamin E may be pertinent to the management of risk reduction for AMD. (Optimal amounts of vitamin E could confound anticoagulant therapy.)





Interactions:

Concomitant administration with beta-carotene may reduce bioavailability of lutein and may reduce or increase bioavailability of beta-carotene.

There are no particular precautions to note when using extracted lutein and zeaxanthin from plant sources. However, increased dietary plant consumption in order to obtain increases in lutein and zeaxanthin, as opposed to lutein/zeaxanthin extract supplementation, may present possible clinical problems in the following medically treated categories:²¹

Negative dietary vitamin K interactions in anticoagulation therapy,

Increased risk for forming kidney stones from dietary oxalic acid, and

Additional exposure to dietary iron in cases of hemochromatosis.

Certain drugs, nutritional supplements, and foods have been reported to decrease the absorption of lutein/zeaxanthin. Cholesterol lowering medications, including cholestyramine, and colestipol, a drug used to treat obesity, may reduce the absorption of fat-soluble carotenoids.²¹

Grape seed extract: May potentiate other herbs and medications that have blood thinning effects. Could present a risk for bleeding in those that use NSAIDs and ASA in high doses or frequently.²³

Ginkgo biloba: May potentiate other herbs and medications that have blood thinning effects. Could present a risk for bleeding in those that use NSAIDs and ASA in high doses or frequently.²³

Bilberry: Preliminary research in animal models suggests that bilberry leaf extract might have blood glucose lowering activity. Theoretically, concomitant use of bilberry leaf might require dosing adjustment of anti-diabetes drugs; monitor closely.²³

Green tea: Green Tea contains caffeine. The caffeine in green tea might increase the risk of additive CNS effects.²³ Concomitant use of herbs and supplements that affect platelet aggregation could theoretically increase the risk of bleeding in some people.²³ Green tea appears to reduce absorption of non-heme iron from foods.²³



Toxicity/Adverse Reactions:

Lutein: Adverse side effects are not associated with these nutrients when consumed at the recommended amounts. Taking capsules on an empty stomach may cause nausea. Adverse side effects or toxicity are not associated with lutein extracts at the recommended amount of this product.²³

Ginkgo biloba: Well tolerated in typical dose. It can cause mild gastrointestinal (GI) upset, headache, dizziness, palpitations, constipation, and allergic skin reactions.²³

Bilberry: None reported.

Grape seed extract: Usually well-tolerated. May cause minor upset stomach.^{11,23}

Green tea: Side effects are rare for most people. Large intake or high doses of green tea can cause insomnia and nervousness. Green tea has been reported to cause liver problems in rare cases.^{11,23}





Allergen Content/Ingredient Sensitivity:

NO	YES
Artificial Colors	Sulphites (<10 ppm)
Artificial Flavors	
Artificial Sweeteners	
Corn Products	
Egg Products	
Fish	
Gluten	
Hydrolyzed Plant Protein	
Lecithin	
Milk Products	
Peanuts	
Preservatives	
Sesame Products	
Shellfish	
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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