Lutein 20 mg Softgels

Product Summary:

Getting older is hard enough without worrying about losing your vision. Age-related macular degeneration (AMD) is the leading cause of vision loss in seniors in North America. Lutein and its naturally occurring stereoisomer zeaxanthin are antioxidants that are used for risk reduction and nutritional intervention in AMD. These cartenoids are also part of a general carotenoid defense against oxidative stress. Lutein may lower the risk of breast cancer and improve its prognosis,[1,2] as well as protecting against skin cancer[3,4] and cataracts.[5]

Properties/Uses:

The claim as approved by the *Natural Health Products Directorate* (NHPD): Lutein is an antioxidant for eye health. It promotes the health of the macula, retina and lens with its antioxidant properties and by filtering out damaging blue light. This may reduce the risk of age-related macular degeneration and cataracts.

EYE

Pharmacology:

Age-related macular degeneration (AMD) 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.[6] 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.[7] Even though AMD is observed to rise sharply with age, it is not strictly a disease of the elderly.[6] At present, there are no effective medical treatments for most patients with the disease.[6]

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.[6,8] A landmark Harvard epidemiology study showed that the risk for further progression of advanced AMD can be reduced directly in proportion to the dietary lutein intake.[9]

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 increase 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.[10] 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 to improve other parameters, such as contrast sensitivity.[11]

The macula is a small circular region on the retina with a 4 to 5 mm radius controlling central vision. Degeneration of the macula leads to central vision blindness, with peripheral vision remaining. Lutein, zeaxanthin, and mesozeaxanthin are the only carotenoids concentrated in the macular region, while beta-carotene is virtually absent from the macula. Lutein is the most prevalent in nature, and therefore in the diet, and its concentration in the plasma usually exceeds that of zeaxanthin by approximately 3:1.[12] However, in the retina the concentration of zeaxanthin and another stereoisomer, mesozeaxanthin, in combination exceed the concentration of lutein by approximately 2:1.[12] Mesozeaxanthin is not found

in the blood, and there is evidence that a chemical process in the retina converts lutein to mesozeaxanthin.[8]

Lutein and zeaxanthin filter blue light, 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 antioxidants, 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 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 slow its progression. When using lutein/zeaxanthin as a treatment to arrest AMD, it is recommended that the consumer consider at least 6 mgs BID and preferably 6 mgs TID. Their eye professional can evaluate the efficacy of this dosage range with adjustments as required.

Manufacturer product information:

Manufacturer:
WN Pharmaceuticals® Ltd.

Size/UPC:
60's 7 77747 10291 4

NPN:
80002546

Expiry Date:
36 months from date of manufacture

Active Ingredient:
Each capsule contains :

Lutein (*Tagetes erecta*) (oleoresin from flower) ..... 20 mg
Zeaxanthin (*Tagetes erecta*) (oleoresin from flower)..... .860 mcg

Non-Medicinal Ingredients (in descending order):
Softgel capsule (gelatin, glycerin, purified water, annatto, titanium dioxide), soybean oil, safflower oil, yellow beeswax, lecithin.

Appearance:
Reddish to orange brown slightly viscous oil encapsulated in a size 4.5 oval opaque reddish coloured soft gelatin shell.

Packaging:
175 cc white round bottle with safety seal under a 38 mm white induction sealed cap with vented interior seal and a label applied to the bottle. Lot number and expiry date are printed on the label applied to the exterior of the bottle. .

Storage:
Store in a cool, dry place.

Dose:

As per the NHPD Monograph for marigold extract, the adult maximum dose for lutein is 20mg/day.[13]

A risk assessment study of lutein stated the Oberved Safe Level (OSL) of lutein is 20mg/day.[14] A later study with used dosages of up to 30mg/day over 6 months safely and without adverse effects.[15]

Directions:

(Adults): 1 softgel daily or as recommended by a physician.

Caution:

The caution as approved by the *Natural Health Products Directorate* (NHPD): KEEP OUT OF THE REACH OF CHILDREN. Do not use if pregnant or breastfeeding. STORE AT ROOM TEMPERATURE IN A DARK, DRY PLACE. DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

Deficiency Symptoms:

Epidemiological studies suggest that lutein deficiency is a major risk factor for AMD.[16] Since lutein and zeaxanthin are the major cartenoid pigments found in the retina, it stands to reason that a deficiency would have a negative impact on eye health. Similar studies suggest a link between decreased consumption of lutein-containing foods and increased risk of chronic diseases.[17]

Drug Interactions/Contraindications:

Do not use if allergic to plants of the Asteraceae/Compositae/Daisy family.

There are no other 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: 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.[18]

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.[19] In one trial 29,133 Finnish men who were smokers and consumers of alcohol, some men received 20 mg per day of beta-carotene while others were untreated. 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 mg (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.[20-22]

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.[20] 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 pre-empt 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.[20] The data might suggest that the protection associated with dietary beta-carotene is likely to be realized in beta-carotene supplements only when complemented with other antioxidant nutrients, thus approximating nature’s network of antioxidation.[20,23] 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.[24]

Based on the negative interaction of supplemented beta-carotene in those who consume alcohol and/or smoke, and in asbestos miners, lutein and zeaxanthin (dihydroxy-betacarotene) may be expected to have similar adverse effects in smokers, drinkers (uncertain as to how much alcohol is required to produce a negative effect with beta-carotene), and asbestos workers who 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.[25] Those with active macular degeneration may want to use up to 18 mg 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. 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.)

Toxicity/Adverse Reactions:

There is insufficient long-term safety data on lutein to say categorically that lutein supplementation cannot have adverse side effects. However, supplemental lutein and zeaxanthin have not been associated with adverse effects, and this is the general picture for all carotenoids.[6] Lutein and zeaxanthin, collectively referred to as the xanthophylls, are dihydroxy-beta-carotene. At the levels commonly used in supplementation, they should have the same safety profile associated with beta-carotene and other carotenoids.

Allergen Content/Ingredient Sensitivity:

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