

# MacularProtect®

## Capsules

### Description

MacularProtect is an antioxidant vitamin and mineral supplement designed to help maintain the health of the macula, the area of the retina where the sharpest central vision occurs. The nutrients in MacularProtect reflect findings from the AREDS and AREDS2 clinical trials, as well as evidence that B-vitamins play a key protective role. Beta-carotene free, it is appropriate for both smokers and non-smokers.

### MacularProtect Highlights

- ▶ Scientific stand-alone formulation for individuals concerned about preserving macular health
- ▶ Contains vitamins C and E, zinc and copper at levels found to support eye health in the AREDS clinical trial
- ▶ Provides 10 mg lutein and 2 mg zeaxanthin, reflecting AREDS2 levels
- ▶ Beta-carotene free – can be used by those who should avoid high intake, including current and former smokers
- ▶ Provides B-vitamins for added macular health protection
- ▶ Manufactured in NSF®-certified facilities from the finest quality, bioavailable ingredients

### AREDS & AREDS 2 Results

AREDS, a long-term clinical trial, reported in 2001 that high-risk category patients supplementing with antioxidants and zinc improved the chance of retaining their macular health status by 25% and preserving their vision by 19%<sup>1</sup>.

The second AREDS trial (AREDS2) examined whether lutein and zeaxanthin (and/or marine omega-3s) taken with the AREDS formula could reduce the risk of progression to advanced age-related macular degeneration (AMD) by an additional 25% compared to taking the AREDS supplement alone. Though lutein and zeaxanthin did not meet the required 25% threshold, analyses showed that these nutrients do offer protection<sup>2</sup>. Based on this, the National Eye Institute (NEI) now

recommends the original AREDS formula, with lutein and zeaxanthin replacing beta-carotene, as the new standard of care for those with at least intermediate AMD.

### Rationale for Inclusion of Key Ingredients

#### Vitamin C (750 mg)

Vitamin C is a water-soluble antioxidant that is concentrated in ocular tissues where it deactivates free radicals. Free radicals are highly reactive compounds produced through the body's use of oxygen and generated by outside sources such as ultraviolet light. Oxidative stress – an imbalance between free radicals and antioxidants – is considered a factor in AMD development and progression<sup>3</sup>. As part of the cellular antioxidant network, vitamin C aids in recycling antioxidants like vitamin E. MacularProtect supplies the form and level used in AREDS, plus an additional 250 mg.

#### Vitamin E (321 mg)

Fat soluble vitamin E is the major chain-breaking antioxidant in retinal and macular membranes. As a first line of defense against fatty acid peroxidation, vitamin E helps protect cell membranes against free radical attack and works synergistically with lutein and zeaxanthin to protect unsaturated fatty acids<sup>4</sup>. MacularProtect provides natural source rather than synthetic vitamin E, as studies demonstrate that this form offers superior bioavailability and is better retained in tissues<sup>6</sup>. It also delivers broad spectrum vitamin E from alpha to gamma tocopherol, that together play a health-protective role<sup>7</sup>. MacularProtect includes 321 mg of vitamin E, the

level used in AREDS.

#### Zinc (80 mg)

Zinc is an essential mineral that is selectively concentrated in the eye. It is found in the retina and choroid, ciliary body, iris, optic nerve, sclera, cornea, and lens. Within these ocular structures zinc is believed to interact with vitamin A and taurine to modify photoreceptor membranes, to help regulate the light-rhodopsin reaction, to influence nerve transmission, and to serve as an antioxidant<sup>8</sup>. MacularProtect provides 80 mg of zinc in the form and amount recommended by the NEI, based on the AREDS and AREDS2 trials.

#### Copper (2 mg)

Copper is essential for normal development of connective tissue, nerve sheaths, skin pigment and for proper iron utilization. Since high zinc levels compete with copper for absorption, copper is included in MacularProtect to help ensure an adequate level of this mineral in the body. MacularProtect provides 100% of the Daily Value of copper in the form and amount used in the AREDS clinical trial.

#### Lutein, FloraGLO® (10 mg) and Zeaxanthin (1 mg)

Lutein and zeaxanthin are similarly structured carotenoids found in green leafy vegetables like spinach and kale. These carotenoids help make up the retina's macular pigment, the body tissue with the highest lutein and zeaxanthin concentration<sup>9</sup>. As part of the macular pigment, these carotenoids filter blue (visible) light that can cause photo-oxidative stress.

Results of several AREDS2 analyses showed these





MacularProtect is a scientific nutritional formulation to help preserve macular health. It is based on the latest research supported by the National Eye Institute and other advanced science.

**Suggested Use:** Take a total of two capsules daily, with meals.

**Note:** Pregnant or lactating women or individuals with medical conditions should consult a physician before using.

MacularProtect contains 80 mg of zinc, a level that was found to support eye health in the AREDS clinical trial. Check with your physician prior to taking MacularProtect to ensure that this level of zinc is appropriate for you. Keep out of the reach of children.

These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

<b>Supplement Facts</b>		
Serving Size 2 capsules	Servings Per Container 30	
	Amount Per Serving	% Daily Value
Vitamin C (as ascorbic acid)	750 mg	833%
Vitamin E (as d-alpha tocopheryl succinate and mixed tocopherols)	321 mg	2,140%
Vitamin B6 (from pyridoxine hydrochloride)	20 mg	1,176%
Folate (50% from folic acid, 50% from calcium folinate)	333 mcg DFE	83%
Vitamin B12 (as cyanocobalamin)	100 mcg	4,167%
Zinc (from zinc oxide)	80 mg	727%
Copper (from copper oxide)	2 mg	222%
Lutein (FloraGLO®)	10 mg	†
Zeaxanthin (from OPTISHARP® & FloraGLO® Lutein)	2 mg	†

† Daily Value not established.

**Other Ingredients:** Bovine Gelatin, Water, Silica and Magnesium Stearate.



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## Lutein and Zeaxanthin (continued)

carotenoids offer macular protection<sup>2</sup>. A comparison of patients who received lutein / zeaxanthin with those who did not showed a beneficial effect of these carotenoids in reducing risk of advanced AMD. Two groups of study participants benefited further. The first had low dietary intake of the carotenoids, which is noteworthy since average lutein/zeaxanthin intake among Americans 50 and older is less than 2 mg daily – far lower than the 12 mg tested in AREDS2<sup>9</sup>.

The second group to benefit were those who received lutein / zeaxanthin but no beta-carotene. Beta-carotene was found to suppress the absorption of lutein / zeaxanthin, which may partly explain these results. Importantly, beta-carotene was observed to double the risk of lung cancer in former smokers<sup>2</sup>. Thus, the NEI recommends a safer and more effective formula by replacing beta-carotene with lutein /zeaxanthin in the original AREDS formula.

## Folic Acid, Vitamin B6 and Vitamin B12

Vitamins B6, B12 and folic acid regulate levels of a compound known as homocysteine in the blood. Elevated levels of this compound can damage the inner lining of small blood vessels, and high levels have been found in AMD<sup>10</sup>. Up to 25% of the elderly are estimated to be B12 deficient, and inadequate blood levels of B6 are common in many<sup>11</sup>.

A large-scale intervention trial reports that high dose supplemental folic acid with vitamins B6 and B12 taken over a 7-year period reduced the likelihood of AMD developing in women with or at risk for heart disease<sup>12</sup>. Results of a 10-year study support these clinical findings, and suggest that more moderate intakes of folic acid and supplemental B12 may lower AMD risk<sup>13</sup>. Participants with elevated blood levels of homocysteine, low levels of folic acid, or B12 deficiency, were at greater risk of developing early or late stage AMD in this study. Those who reported taking B12 supplements were considerably less likely to develop the disease. MacularProtect provides robust levels of these key B-vitamins.

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