



## The AREDS Formulation and Age-Related Macular Degeneration

### Are These High Levels of Antioxidants and Zinc Right For You?

The Age-Related Eye Disease Study (AREDS) - sponsored by the Federal government's National Eye Institute - has found that taking high levels of antioxidants and zinc can reduce the risk of developing advanced age-related macular degeneration (AMD) by about 25 percent.

This major clinical trial closely followed about 3,600 participants with varying stages of AMD. The results showed that the AREDS formulation, while not a cure for AMD, may play a key role in helping people at high risk for developing advanced AMD keep their remaining vision.

But is the AREDS formulation right for you? Here are some questions and answers that can help you make that decision.

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### Who Should Take the AREDS Formulation?

People who are at high risk for developing advanced AMD should consider taking the combination of nutrients used in the study. Your eye care professional can tell you if you have AMD and are at risk for developing the advanced form of the disease. The doctor should give you a dilated eye exam in which drops are placed in your eyes. This allows for a careful examination of the inside of the eye to look for signs of AMD.

Before taking these high levels of vitamins and minerals, you should talk with your doctor about the risk of developing advanced AMD and whether taking the AREDS formulation is right for you.

### What is the Dosage of the AREDS Formulation?

The specific daily amounts of antioxidants and zinc used by the study researchers were 500 milligrams of vitamin C; 400 International Units of vitamin E; 15 milligrams of beta-carotene (often labeled as equivalent to 25,000 International Units of vitamin A); 80 milligrams of zinc as zinc oxide; and two milligrams of copper as cupric oxide. Copper was added to the AREDS formulations containing zinc to prevent copper deficiency anemia, a condition associated with high levels of zinc intake.

### Can I Take a Daily Multivitamin if I Am Taking the AREDS Formulation?

Yes. A daily multivitamin contains many important nutrients not found in the AREDS formulation. For example, elderly people with osteoporosis need to be particularly concerned about taking vitamin D, which is not in the AREDS formulation. The AREDS formulation is not a substitute for a multivitamin. In the Age-Related Eye Disease Study, two-thirds of the study participants took multivitamins along with the AREDS formulation.

If you are already taking daily multivitamins and your doctor suggests you take the AREDS formulation, be sure to review all your vitamins with your doctor before you begin.

Can a Daily Multivitamin Alone Provide the Same High Levels of Antioxidants and Zinc as the AREDS Formulation?

No. The AREDS formulation's levels of antioxidants and zinc are considerably higher than the amounts in any daily multivitamin.

### Can Diet Alone Provide the Same High Levels of Antioxidants and Zinc as the AREDS Formulation?

No. The high levels of vitamins and minerals are difficult to achieve from diet alone. However, previous studies have suggested that people who have diets rich in green, leafy vegetables have a lower risk of developing AMD.

#### Will Taking the AREDS Formulation Prevent a Person from Developing AMD?

No. There is no known treatment that can prevent the development of AMD. The study did not show that the AREDS formulation prevented people from developing early signs of AMD. No recommendation has been made for taking the AREDS formulation to prevent early AMD.

Taking the formulation reduced the rate of advanced AMD in people at high risk by about 25 percent over a 6-year period. We do not know if this treatment effect will persist over a longer period. However, by continuing to follow the AREDS participants, we hope to find out if the treatment effect will last longer than six years.

#### Where Can I Buy the AREDS Formulation?

You can purchase the AREDS formulation at drug stores, supermarkets, health food stores, and other retail outlets that sell pharmaceutical products. The vitamins and minerals can also be purchased separately; be certain to include copper whenever taking high levels of zinc. Taking beta-carotene is not recommended for smokers.

#### Are There Any Side Effects from the AREDS Formulation?

Some AREDS participants reported minor side effects from the treatments. About 7.5 percent of participants assigned to the zinc treatments - compared with five percent who did not have zinc in their assigned treatment - had urinary tract problems that required hospitalization. Yellowing of the skin, a well-known side effect of large doses of beta-carotene, was reported slightly more often by participants taking antioxidants.

#### Are Former Smokers at an Increased Risk for Developing Lung Cancer if They Take High Doses of Beta-Carotene?

Large clinical trials sponsored by the National Cancer Institute demonstrated that beta-carotene increases the risk of lung cancer in current smokers. In these trials, most of these smokers were heavy smokers. The only other large clinical trial evaluating beta-carotene was the Physicians Health Study (PHS). In the PHS, there was no evidence of increased cancer risk in those randomly assigned to beta-carotene, but few physicians were active smokers. There also was no evidence of an increased risk of lung cancer in former smokers.

However, many studies suggest that former smokers maintain some increased risk of lung cancer for years after stopping smoking. Therefore, it is reasonable to expect that beta-carotene may also slightly increase their risk of cancer, at least for a period of several years.

In deciding whether to include beta-carotene in a formulation designed to slow the development of advanced AMD, you and your doctor should balance the apparent increase in the risk of lung cancer associated with beta-carotene with the risk of AMD progression.

#### **What About Other Antioxidants Such as Bilberry and Lutein?**

The AREDS did not study bilberry, lutein, or other antioxidants, so we don't know how they may affect eye disease. Future clinical trials may eventually provide answers about these or other antioxidants.

#### **Should Young People with Inherited Macular Degeneration Take the AREDS Formulation?**

The AREDS only studied age-related macular degeneration. We have no recommendations for younger people with the inherited (juvenile) forms of macular degeneration.

#### **Where Can I Obtain More Information?**

For more information, contact your eye care professional or the National Eye Institute at 301-496-5248 or visit the NEI website at [www.nei.nih.gov/amd](http://www.nei.nih.gov/amd).

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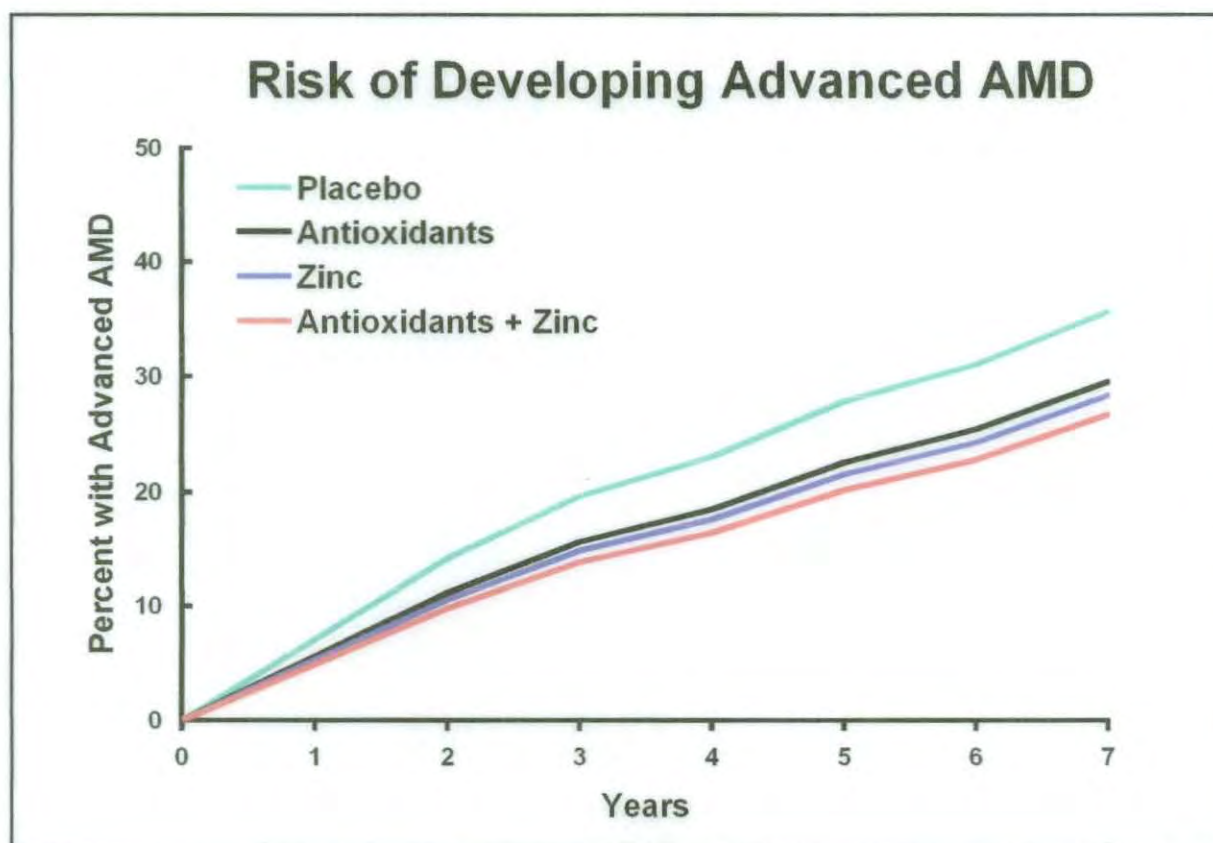
## **Researchers say green leafy vegetables may help protect eyes from AMD, cataracts.**

In continuing coverage from previous editions of *First Look*, the Atlanta Journal-Constitution (3/5, O'Neil) reported that researchers are investigating "the link between what we eat, and the long-term health of our eyes." One interesting finding has been the discovery that the "body converts the beta-carotene in carrots into vitamin A, which aids night vision." But, while "[c]arrots still rank high on the eyesight-saving menu," researchers are focusing "on green leafy vegetables such as spinach, kale, collard greens, and turnip greens because they contain two natural carotenoid plant pigments called lutein and zeaxanthin." The pigments "are potent anti-oxidants thought to protect the eyes against damaging free radicals that may cause cataracts and age-related macular degeneration." In a recent study, Harvard Medical School researchers "found that women who consumed higher levels of lutein and zeaxanthin (6.7 milligrams per day) were 18 percent less likely to develop cataracts than those who consumed lower levels of the anti-oxidants (2.1 milligrams per day).

## Age-related Macular Degeneration

For those study participants who initially had early AMD (Category 2), less than two percent developed advanced AMD over five years. Without treatment, those with intermediate AMD had an 18 percent chance of developing advanced AMD in one or both eyes over 5 years, and those with advanced AMD in only one eye had a 43 percent chance of developing advanced AMD in the other eye. AREDS scientists found that

people at high risk for developing advanced stages of AMD — that is people with intermediate AMD or advanced AMD in one eye — lowered their risk by about 25 percent when treated with the tablets containing "antioxidants plus zinc" compared to placebo. The graph shows the percent of people who developed advanced AMD during the study by treatment assignment.



In the same high-risk group — which includes people with intermediate AMD or with advanced AMD in one eye but not the other eye — the "antioxidant plus zinc" tablets reduced the risk of moderate or severe vision loss by about 19 percent.

This is an exciting discovery because it means that the "antioxidant plus zinc" tablets are the first effective treatment to *slow the progression* of AMD and/or vision loss for people who are at high risk for developing advanced AMD. The graph shows the percent of people losing 15 letters or more (3 or more lines) of vision on the vision chart by treatment assignment.

Participants at high risk for developing advanced AMD who took the "zinc alone" tablets reduced this risk by about 21 percent and their risk of vision loss by about 11 percent. Participants who were treated with the "antioxidants alone" tablets reduced their risk of developing advanced stages of AMD by about 17 percent and their risk of vision loss by about 10 percent.

