

# Vitamin E 400 IU Softgels



## Product Summary:

Oxidative stress is a major factor in many diseases and leads to the production of free radicals in the body. Vitamin E is a powerful antioxidant that decreases oxidative stress and thereby reduces the formation of free radicals. This antioxidant is used in the treatment of cardiovascular disease, diabetes, age-related macular degeneration and other diseases and conditions.

## Properties/Uses:

The claim as approved by the *Natural Health Products Directorate* (NHPD): An antioxidant for the maintenance of good health.



GENERAL HEALTH  
& WELLNESS



## Pharmacology:

Vitamin E is a very powerful lipid-soluble antioxidant. Antioxidants are necessary to prevent oxidative damage in the body and therefore diminish the formation of free radicals. Oxidative damage plays a major role in the development of Alzheimer's disease, cancer, as well as diabetes. Vitamin E can contribute to the reduction of these and other conditions.

The principal use of vitamin E is as a lipid-soluble antioxidant, acting at the level of cellular membranes and plasma lipid-carrier membranes to break free-radical initiated peroxidation chain reactions in phospholipid polyunsaturated fatty acids. It is considered to be the premiere membrane antioxidant.<sup>1,2</sup>

Vitamin E provides documented anti-atherogenesis effects including reduced oxidative damage of LDL cholesterol, improved plasma LDL breakdown, enhanced control over platelet aggregation, increased HDL levels, and increased fibrinolytic activity.<sup>3</sup> Damaged LDL cholesterol can lead to atherosclerosis.<sup>4</sup> In one large epidemiological study a low level of vitamin E was found to be a greater risk for heart attack and stroke than cholesterol. High cholesterol had a causal correlation with heart attack in 29 per cent of studied cases, while high blood pressure presented a causal correlation in 25 percent of cases. However, low vitamin E levels were predictive in 70 percent of cases.<sup>5</sup> Many large-scale studies have concluded that vitamin E supplementation reduces the risk of heart attacks and ischemic stroke.<sup>4</sup>

Diabetics have an increased need of vitamin E. Like vitamin C, it is critical to reducing or holding at bay the complications of diabetes. Double-blind studies have shown that vitamin E not only increases insulin action, but also increases glucose metabolism.<sup>4</sup> Membrane integrity is central to reducing insulin resistance, which is at the heart of Type II pathology, but also impacts on long standing Type 1 diabetes.<sup>3</sup>

Observational and experimental data suggest that antioxidant supplements may delay progression of age-related macular degeneration (AMD) and vision loss. A randomized, placebo-controlled clinical trial was conducted to evaluate the effect of vitamins C and E, beta-carotene and zinc supplements on AMD progression and visual acuity. The Age-Related Eye Disease Study found that taking 400 IU vitamin E, 80 mg zinc, 500 mg vitamin C, and 15 mg beta-carotene decreased the risk of AMD by 25%.<sup>6</sup>

Vitamin E is used to enhance immune system performance. It is also used medically to treat a variety of problems associated with vitamin E deficiency, usually due to long-term compromised fat absorption, or in very large doses to treat degenerative conditions including muscle degeneration and rheumatic joint disease. Vitamin E is also being investigated for decreasing the occurrence of Parkinson's disease.<sup>7</sup> It has also been used to improve symptoms in patients with early Huntington's disease.<sup>7</sup>



Maximum vitamin E intake obtained from diet alone typically only reaches 60 IU per day. Supplementation of vitamin E can increase serum levels so as to contribute more antioxidant benefit.

### *Natural Versus Synthetic Vitamin E*

Synthetic vitamin E (dl-alpha tocopherol), and its acetate ester, has been shown to have lower biological activity than naturally occurring d-alpha tocopherol and its acetate ester. The table below shows the commonly understood activity relationships between the various d-alpha and dl-alpha stereoisomers.<sup>3</sup>

VITAMIN E ISOMER	BIOLOGICAL ACTIVITY	MG PER 400 IUs
d-alpha tocopherol	1.49	268
d-alpha tocopheryl acetate	1.36	294
dl-alpha tocopherol	1.1	364
dl-alpha tocopheryl acetate	1.0	400
d-beta tocopherol	0.60	
d-gama tocopherol	0.15-0.45	
d-delta tocopherol	.015	

From the table it can be seen that 400 mg of dl-alpha tocopheryl acetate defines 400 IU. Fewer milligrams of d-alpha tocopherol or d-alpha tocopheryl acetate are required to equal the biological activity of 400 IU dl-alpha tocopheryl acetate. The two d-alpha versions respectively present 49% and 36% greater biological activity. The listed activities are the accepted ratios of how the different stereoisomers performed biologically in conventional standardized animal testing comparing each stereoisomer to dl-alpha tocopheryl acetate, which standardized testing includes absorption and retention considerations.

However, in the April 1998 issue of the American Journal of Clinical Nutrition, study results were published that indicated that the more realistic biological activity ratio of the natural to the synthetic versions of alpha-tocopherol in humans is essentially 2.0. The available experimental data suggests that the greater biological activity of natural relative to synthetic alpha-tocopherol is due to the preferential enrichment of VLDL by stereo-selectivity of the natural d-stereoisomer, via a liver tocopherol transfer protein (TTP), and subsequently involving other circulating lipoproteins, with an ultimate selective delivery of the natural stereoisomer to the tissues by these lipoproteins. Furthermore, the research found that over time the l-stereoisomer that was initially distributed to the tissues was poorly retained and was selectively and over time eliminated in the bile due to natural vitamin E cycling, with a tissue retention of predominately the natural d-alpha-tocopherol.<sup>8</sup>



This research calls into question the practice of equating the natural and the synthetic retail versions simply because the respective softgel capsules are filled gravimetrically in such a way that each delivers 400 IU irrespective of the source. The conventional basis of international units stems from animal comparisons, that appear to not represent human conditions. And consumers who chose synthetic vitamin E, ultimately obtain less biological value for their money, simply because the stereoselectivity of the liver transfer protein “ignores” the bulk of the l-alpha isomer, and selectively fails to retain it. Over time (approximately 1 to 2 years and beyond), using synthetic vitamin E delivers about half the antioxidation value of using the natural. Since using vitamin E for all-body health enhancement is a life long matter, this difference can be considered to be of practical significance.





## Manufactured product information:

**Manufacturer:**

WN Pharmaceuticals® Ltd.

**Size/UPC:**

120's ..... 7 77747 10337 9

**NPN:**

2237077

**Expiry Date:**

54 months from date of manufacture

**Active Ingredient:**

Each softgel contains:

Vitamin E (d-alpha tocopheryl acetate) ..... 268 mg AT\* (400 IU)

\*Alpha Tocopherol

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

Softgel capsule (gelatin, glycerin, purified water), soybean oil.

**Appearance:**

Clear yellowish oil encapsulated in a size 7.5 oval clear 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 label applied to exterior of bottle.

**Storage:**

Preserve in tight containers in a cool dry place. Do not refrigerate. Protect from heat and light.





## Dose:

According to the NHPD, the daily dose of vitamin E for children 1-3 years is 0.6-200 mg AT, children 4-8 years is 0.6-300 mg AT, adolescents 9-13 years is 0.6-600 mg AT, adolescents 14-18 years is 1-800 mg AT, and adults is 1-1000mg AT.<sup>9</sup>

The recommended optimal amount of vitamin E accepted by a broad range of health care professionals is 400 to 800 IU per day, preferably in divided amounts in the case of 800 IU per day, and with meals.<sup>3</sup>

A daily amount of 400 IU is quite acceptable if vitamin C is also supplemented.<sup>1,3</sup>

## Directions:

**(Adults):** 1 – 2 softgels 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. Consult a physician prior to use if you are taking blood thinners, or if you have cardiovascular disease, diabetes or cancer. STORE AT ROOM TEMPERATURE IN A DARK, DRY PLACE. DO NOT USE IF SEAL UNDER CAP IS BROKEN OR MISSING.

## Deficiency Symptoms:

Vitamin E deficiency is rare. Those who do not absorb fat well are at risk of developing a vitamin E deficiency. True deficiency of vitamin E leads to serious neurological damage and erythrocyte fragility. Malabsorption of fat should be suspected in those who have “fatty” diarrhea regularly.<sup>9</sup> In premature infants, vitamin E deficiency can cause irritability, edema, thrombosis, and hemolytic anemia.<sup>7</sup>





## Drug Interactions /Contraindications:

Vitamin E is contraindicated in anti-coagulation therapy, unless prescribed by a physician.

Because vitamin E can interfere with vitamin K uptake, it can confound control of anticoagulant medications that lower vitamin K like Coumadin, unless prescribed by a physician.<sup>10</sup> Vitamin E is also involved in the production of prostacyclin, which is an intrinsic anti-aggregation factor. As well, vitamin E facilitates fibrinolytic activity.<sup>3</sup>

High intake levels of vitamin E reduce the intestinal absorption of vitamin K, and can confound the management of effective anticoagulant drug therapy based on vitamin K manipulation, as with Coumadin. Apart from anticoagulant drug therapy, vitamin E has not been found to produce coagulation abnormalities in those who are not vitamin K deficient.<sup>11</sup>

Ferrous iron destroys vitamin E. They should be taken at different times sufficiently separated to avoid interaction.

High simultaneous intake of vitamin A may interfere with vitamin E absorption.

Some anticonvulsants including phenobarbital, phenytoin, and carbamazepine significantly lower plasma vitamin E levels by altering absorption, distribution and metabolism.<sup>12</sup>

Vitamin E and vitamin C interact beneficially with C regenerating E, making it again active as a membrane radical chain-breaking antioxidant. However, there is evidence that vitamin C can act as a pro-oxidant, especially in the presence of iron, if adequate levels of vitamin E are not present.<sup>13</sup> The optimal dose range of vitamin C should be encouraged, but with equal attention to an optimal dose range of vitamin E, which many experts in natural medicine would say is 200 to 800 IUs per day.

Selenium interacts with vitamin E beneficially, enhancing its action. The daily recommended dosage of selenium is 200 micrograms. This interaction stems from its role in glutathione regeneration of vitamin E in conjunction with the enzyme glutathione peroxidase, which incorporates four atoms of selenium. Selenium is also involved in the production of thioredoxin, which regenerates vitamin C, which in turn regenerates vitamin E.<sup>1</sup>



## Toxicity/Adverse Reactions:

Human studies and experience show that adverse side effects from vitamin E is virtually nonexistent when used in a dosage range up to 720 mg per day.<sup>2</sup> At doses above 720 milligrams, and particularly doses of 1600 to 3000 mg/day, side effects can occur with prolonged use, and documented side effects include gastrointestinal complaints, creatinuria, and impaired blood coagulation, which subside rapidly with dose reduction.<sup>2</sup>

In human studies with double-blind protocols and other large studies with oral use of vitamin E, few adverse side effects have been reported, even with doses as high as 3200 IU/day (natural vitamin E), or when use of vitamin E has been long term. Tests for mutagenicity, carcinogenicity, and teratogenicity have proved negative.<sup>2</sup>





## Allergen Content/Ingredient Sensitivity:

NO	YES
Artificial Color	Soy Products
Artificial Flavor	Sulphites (<10 ppm)
Artificial Sweeteners	
Corn Products	
Egg Products	
Fish	
Gluten	
Hydrolyzed Plant Protein	
Lecithin	
Milk Products	
Peanuts	
Preservatives	
Sesame Products	
Shellfish	
Tartrazine	
Tree Nuts	
Wheat Products	
Yeast	

### NOT ACCEPTABLE FOR THE FOLLOWING DIETARY RESTRICTIONS:

Free of animal products

Kosher





## References

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11. Kataoka K, *et al.* Vitamin E status in pediatric patients receiving antiepileptic drugs. Dev Pharmacol Ther 1990;14:96-101.
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