



NSK-SD™ nattokinase

Special Feature

An Interview with Dr. Ralph Holsworth, D.O.

Q: *What is your background and involvement with NSK-SD™ nattokinase?*

A: I am a board-certified family medicine osteopathic physician who has clinically researched enzymes for the last 10 years. I was the first U.S. physician to use nattokinase (specifically NSK-SD™) in a hospital and clinical setting and introduced it to the U.S. medical community in 2001. I have met the discoverer of nattokinase, Dr. Hiroyuki Sumi, on two occasions in order to collaborate and expand on the clinical and laboratory research. Based on my findings, I submitted nattokinase (NSK-SD™) to the FDA in 2002 as a medical food. My clinical research has focused on the value of nattokinase in maintaining healthy whole blood viscosity and blood perfusion for cardiovascular health.

Q: *Can you give us a brief overview of what nattokinase is and how it works?*

A: Nattokinase is a naturally-occurring proteolytic enzyme derived from natto, a traditional Japanese food produced from the fermentation of soybeans with *Bacillus subtilis natto*. Basically, it is an enzyme that digests fibrin both directly and indirectly. Indirectly, it activates pro-urokinase and tissue plasminogen activator (t-PA), supporting the fibrinolytic activity of plasmin. These combined actions promote healthy platelet function, circulation and blood flow. I would say, in general, that about 10% of its affect is based on direct fibrinolytic activity whereas 90% is based on its ability to upregulate the plasminogen system.

Q: *What types of individuals benefit from nattokinase supplementation?*

A: Men and women in their forties should supplement with nattokinase routinely to maintain healthy whole blood viscosity, which increases with age. Particularly, individuals who need support for blood vessel function,

homocysteine metabolism, healthy clotting function and lipoprotein metabolism are groups that nattokinase can provide key support for.

Q: *What is the optimal recommendation for nattokinase use?*

A: NSK-SD™ is standardized to greater than 20,000 FU (fibrin units) per gram. Usage should be 2,000-4,000 fibrin units per day. This should be divided into two doses because the half life is 8-12 hours. It is best taken immediately following a meal. It should not be combined with other enzymes. One dose should be in the morning and one dose in the evening. Taking nattokinase in the evening is especially important since that tends to be the time that PAI-1 (plasminogen activator inhibitor-1) naturally increases in the body. PAI-1 interferes with the body's innate ability to produce plasmin and therefore degrade fibrin.

Q: *Other forms of nattokinase have been expressed in different units. Why is this?*

A: Currently, some companies express nattokinase activity in terms of "i.u." This is a completely different measure than FU, which indicates nattokinase activity with regards to the degradation of fibrin. The FU is officially adopted by the Japan Health Food Authorization (JHFA) and the Japan Nattokinase Association (JNKA) and is the only true standard for measuring nattokinase activity.

Q: *NSK-SD™ does not contain vitamin K, which is not the case for other forms of nattokinase. Is the sole purpose of this to ensure that the product is not contraindicated with Coumadin?*

A: Yes, the removal of vitamin K from natto used to develop NSK-SD™ is a patented process designed to avoid any potential adverse scenario



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or drug reaction with Coumadin. Vitamin K affects the coagulation cascade by influencing coagulation factors II, V, VII and IX. Furthermore, menaquinone-7, the form of vitamin K₂ naturally found in natto, has a half life of over 48 hours, increasing the concern for potential drug reactions. Dr. Sumi had the foresight to be concerned about this. As a result, NSK-SD™ contains less than 50 parts per trillion vitamin K. Nattokinase works on the plasmin-activation system, a separate and independent mechanism. This is why NSK-SD™ nattokinase in and of itself is not contraindicated with Coumadin.

Q: *Some of our customers have been critical of the amount of published human research on nattokinase. How would you respond to this?*

A: Clinical trials have been completed in the U.S. and are being prepared for publication in a peer-reviewed medical journal. I am preparing clinical and laboratory studies which will complete the pharmacokinetics, dose/response curves and applications. In Siena, Italy, I also recently presented laboratory research from the University of Southern California's Keck School of Medicine demonstrating nattokinase's ability to support healthy whole blood viscosity and red blood cell function, maintaining healthy clotting mechanisms. Miyazaki Medical College of Japan has performed a human study and also collaborated with JCR Pharmaceuticals and Oklahoma State University for another, both trials suggesting support for healthy clotting function and blood flow. In addition, a recent study in east India indicated the ability of nattokinase supplementation to support blood flow in subjects.

There are also hundreds of case studies that I am working to compile. Thousands of individuals in the U.S. use nattokinase. Its use in Japan is four or five times the use in this country.

As a note, the actual biochemical name for the nattokinase enzyme is Subtilisin NAT, for which there are hundreds of studies.

Q: *How can health professionals monitor the effect of nattokinase supplementation?*

A: Follow up blood pressure monitoring with their health professional is important, especially if they are also taking medications for hypertension (due to a potential synergistic effect). Some health professionals are interested in measuring clotting

time. For my research purposes, I use a viscometer, which measures blood viscosity. Unfortunately, this isn't available commercially yet.

Q: *Can you expand on the safety profile of NSK-SD™?*

A: Nattokinase works to up-regulate the body's natural plasminogen system, which regulates itself. Because of this, nattokinase does not circumnavigate the body's own checks and balances. Studies examining the effect of nattokinase administration on tissue plasminogen activator (tPa), euglobulin lysis time, fibrin degradation products and blood fluidity tests have not revealed contraindications on these parameters, though all individuals are different. In my practice, I have occasionally measured euglobulin lysis time (ELT). ELT indicates the activity of plasmin. I have not observed indications of excessive activity of the plasminogen system in the individuals I have tested. Furthermore, an acute toxicity study demonstrated that nattokinase was safe at levels hundreds of times greater than the recommended human dose.

Q: *What about individuals taking antihypertensive medications, fibrinolytic agents or aspirin...are these contraindicated with nattokinase?*

A: Nattokinase is not contraindicated with these, although close medical supervision is always suggested.

Q: *A number of supplements also influence platelet function and fibrinolytic activity, including fish oil, coq10, ginger, garlic, bromelain, pycnogenol, ginkgo, vitamin E, and vitamin C...are these safe to combine with nattokinase?*

A: Again, nattokinase's mechanism of action is very different and it is safe to combine it with these types of products. It is advised, however, that other enzymes not be taken while supplementing with nattokinase. This preserves its full potential by not forcing it to compete for absorption.

Q: *Is it contraindicated for anyone?*

A: Due to potential synergistic effects, concurrent use with anticoagulant and blood pressure medications should be closely supervised by a health professional. It is contraindicated for individuals with a history of bleeding tendency or with conditions associated with bleeding.

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