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Product Review: Review of Cholesterol-Lowering Supplements (Plant Sterols and Policosanol)

Initial Posting: 3/17/10 Updated 3/3/12

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Update:

Problem Found with Another Sterol Supplement: (4/14/12) Plant sterols, such as beta-sitosterol, can not only help treat high cholesterol but also symptoms of prostate enlargement (BPH). Consequently, some beta-sitosterol supplements were also tested in ConsumerLab.com's Product Review of Prostate Supplements. One of these products listed a dose and serving instructions particularly suited for cholesterol-lowering. Testing, however, showed its tablets would not break apart properly (disintegrate) in solution, despite containing the listed amount of sterols. Be aware that, for this reason, *Source Naturals Mega Strength Beta Sitosterol*, is Not Approved by ConsumerLab.com.

What They Are:

According to the American Heart Association, 102.2 million Americans age 20 and older (almost 50 percent of American adults) have elevated blood cholesterol levels, a key risk factor for heart disease. Lifestyle changes such as improving diet, losing weight and increasing exercise are often effective. However, various supplement ingredients may be helpful as well, lowering low-density lipoprotein (LDL or "bad cholesterol"), raising high-density lipoprotein (HDL or "good cholesterol"), and improving the LDL/HDL ratio. Some supplements may also reduce triglycerides.

Supplement ingredients that have been used to reduce cholesterol include sterols and sterol esters (produced in the normal refinement of vegetable oils, or alternatively as a byproduct of papermaking from the oil of pinewood pulp), stanols and stanol esters (substances closely related to sterols that are derived from the same sources), red yeast rice (a yeast grown on rice), high doses of niacin (a B-vitamin), policosanol (a waxy substance from sugar cane, beeswax, wheat germ or rice bran wax), guggulsterone (a gum resin from a tree sap), garlic, fish oil, and soy protein. Soluble fiber in the diet as well as moderate intake of alcohol can also improve cholesterol

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levels.

What They Do:

The amount of evidence supporting the various cholesterol-lowering supplements varies. The best evidence is for sterols, stanols and their esters, soy protein and high dose-niacin (sold as a supplement as well as a prescription drug). Be aware, however, that there are safety concerns regarding the use of some of them. Below is a summary of information about several of the most popular ingredients used for cholesterol-lowering. See ConsumerTips™ for more information about the forms, suggested dosage, and safety considerations. In addition to the uses indicated above, these ingredients have other potential actions and uses (see the links below to the Natural Product Encyclopedia on this site).

Ingredient For an article from the encyclopedia on this site, click on "Article" below	Purported Use	Evidence	Safety	Dosage and Tips for Buying and Using	
DHA and EPA (Omega-3 Fish/Marine Oils) See Product Review and Article	Does not affect LDL but can to significantly decrease triglycerides and might raise HDL slightly. (Harris 1997; Woodman 2002)	Fairly strong.	Considered safe, but could theoretically cause blood thinning problems at high doses (3 grams or more).	Dosage & Tips	
Garlic See Product Review and Article	Small reductions in total cholesterol, LDL and triglycerides in early studies. More recent studies show little benefit. (Khoo 2009)	Inconsistent.	Generally safe, but may thin blood and may interact with drugs used for HIV infection.	Dosage & Tips	
Guggulsterone See <u>Article</u>	Claimed to reduce LDL and triglycerides, but current balance of evidence does not consistently support efficacy in Western diet; the most recent and best designed study found that guggulsterones worsened cholesterol profile by increasing LDL. (Szapary 2003; Ulbricht 2005)	Weak and Inconsistent.	May cause skin rash and other mild side effects. One case report of potential muscle breakdown (rhabdomyolysis).	May Typical dosage is 75 to 100 mg of guggulsterones in the E and Z forms, divided into three dose daily.	
Niacin See Product Review and Article	When taken at very high dose, niacin can markedly improve cholesterol profile, especially HDL, which it can raise by about 35%. Also decreases LDL by about 10% and triglycerides by about 25%. (Al-Mohaissen 2010)	Very strong.	At recommended dose can cause skin tingling, flushing and potentially dangerous liver inflammation.	Dosage & Tips	
Pantethine See Article	Some studies suggest modest decrease in	Inconsistent.	May increase risk of bleeding by	Typical dosage	

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	total cholesterol, LDL, and triglycerides with rise in HDL. (<u>Arsenio</u> 1986)		decreasing platelet aggregation.	to four times daily.
Policosanol See <u>Article</u>	Studies from Cuba suggest that policosanol from sugarcane can significantly lower total cholesterol and LDL. However, all studies outside Cuba failed to find this effect. Other forms of policosanol, such as beeswax- or wheat germ- derived, have undergone relatively little study. (Berthold 2006; Kassis 2006; Kassis 2009)	Inconsistent.	Blood-thinning effects. Otherwise, generally thought to be safe, but not well studied.	Dosage & Tips
Red Yeast Rice See Product Review and Article	Contains naturally occurring lovastatin, a prescription drug used to lower cholesterol; also contains numerous related chemicals that may be active. Like statin drugs, red yeast rice appears to lower total cholesterol, LDL, and triglycerides, while leaving HDL unchanged. (Liu 2006)	Fairly strong. Studies have shown over 20% decline in LDL. But ConsumerLab.com tests show 100-fold variation across marketed products.	Presumably carries the same serious risks as statin drugs, although a recent study showed that only 7% of statin-intolerant people reported muscle pain when switched to red yeast rice (Becker 2009). CL also found several products contaminated with a potential kidney toxin-citrinin. Should not be used in conjunction with statins, niacin, or drugs in the fibrate family.	No longer marketed with standardized lovastatin levels in U.S. due to legal issues. Now sold without lovastatin levels declared.
Soy Protein See Product Review and Article	When taken in adequate doses, appears to modestly lower total cholesterol and improve LDL/HDL ratio. (Zhan 2005)	Fairly strong evidence.	Generally safe when consumed as a food; concentrated extracts could cause hormonal effects, particularly in post-menopausal women.	A typical dose is 20-50 grams per day.
Sterols and Stanol Esters See more in this Review and in Article	Review of studies found 9% decrease in LDL on average (up to 15% has been reported) (Demonty 2009). Do not affect HDL.	Very strong. Work predominately by reducing the absorption of dietary cholesterol in the gut, though can also eliminate cholesterol that the liver recycles through the gut.	Generally safe. Has additive effect with statins.	Dosage & Tips
Sytrinol TM (Proprietary blend of citrus polymethoxy-lated flavones and palm	Preliminary studies suggest reductions of 20-30% in total cholesterol,19-27% in LDL, and 24-34% in	Evidence is preliminary (two open label studies and one controlled study). (Roza 2007)	Generally well tolerated.	Typical dosage is 300 mg per day.

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tocotrieno	ls) triglycerides.		

In this Product Review, testing focused on two of the supplement ingredients noted above: policosanol and sterols. Reviews for fish oils (DHA and EPA), garlic, niacin, red yeast rice, and soy protein have been conducted and are posted elsewhere on this site. Stanols were not tested because the necessary chemical standards were not available. For more information see How Products were Selected.

Quality Concerns and What CL Tested for:

Neither the FDA nor any other federal or state agency routinely tests supplements for quality prior to sale or on the market. ConsumerLab.com tested each of the products listed in the table below to confirm the amount of its key ingredient and other quality parameters as follows:

For policosanol: Policosanol is a mixture of long chain alcohols from sugar cane or rice bran wax. Consistent with most clinical studies done, products were expected to contain at least 55% octacosanol along with certain other long chain alcohols.

For sterols: The FDA permits sterol-containing products to claim that they help reduce the risk of heart disease when used with a diet low in saturated fat and cholesterol. To make the claim, the the product must provide a total of 800 mg of free sterols (1.3 grams of sterol esters) divided into at least two servings per day and taken with meals. Products making the "heart disease" health claim were expected to meet these requirements.

All products were tested to be sure that they did not exceed acceptable levels for lead contamination (which can occur in plant-based products). All tablet and caplet products were tested for their ability to disintegrate, i.e., break apart, so that they could properly release their contents for use by the body.

What CL Found:

Phytosterols:

All of the supplements contained their claimed amount of sterols, providing 800 mg or more of free sterols per day, consistent with what has been shown to be effective. However, one product, CholestaPro, did not pass disintegration testing -- it failed to fully break apart in the 30 minute time period established by the USP (see image below). In fact, even when given 6 hours, the pills would not break apart, suggesting that that it would pass through the body intact and not deliver its ingredients or potential benefits to your body.



Photo: ConsumerLab.com

Before and after (right) disintegration testing. Normally, the pill would not remain intact.

CholestaPro also failed to comply with FDA requirements in its claim to reduce heart disease. CholestaPro suggested use indicated the product should be taken once daily, while sterol products should be taken at least twice a day to increase their effectiveness. In addition to the problems discovered by ConsumerLab.com, CholestaPro's distributor, Central Coast Nutraceuticals, Inc. entered into a \$1.375 million consent agreement with the State of Arizona in June 2009 for deceptive online marketing practices. The product no longer appears to be available through online retailers.

Several of the products that passed testing contained ingredients in addition to sterols and stanols which may have added value but, to our knowledge, these

specific combinations have not been clnically tested:

- -- Centrum Cardio combined sterols with a multivitamin/multimineral formula and a large amount of vitamin B-12 (3,333% of the Daily Value). Although vitamin B-12 may help lower levels of homocysteine (which can be elevated in heart disease), it does not reduce the risk of heart disease nor does it lower cholesterol levels. The sterols in this product may potentially inhibit the absorption of the fat-soluable vitamins also in the formula (beta-carotene, vitamin D, and vitamin E).
- -- Enzymatic Therapy Cholesterol Shield includes pantethine, which may also lower cholesterol.

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- -- Vitamin Shoppe Advanced Cholesterol Formula includes SytrinolTM which may also lower cholesterol, and turmeric and olive fruit extract, both of which may help prevent LDL oxidation (LDL oxidation is associated with the process of atherosclerosis).
- -- Windmill Rx Premium Plant Sterol Cholesterol Control included a dose of garlic (300 mg twice a day) which may also lower cholesterol. It also included a small amount of policosanol (5 mg per two pills) -- much less than the standard dose.

Policosanol:

All of the products contained their claimed amounts of policosanol, which ranged from 20 to 40 mg per day. None of the products claimed other active ingredients. Most products were (or appeared to be) made from sugar cane policosanol. The only notable difference among the products is that *Nature's Life* may be somewhat more convenient to use, as it consists of tiny tablets packaged in a small glass vial. The other products are small capsules.

See Testing Methods and Passing Score for more information about the testing and criteria.

Test Results by Product:

Listed below are the test results for twelve supplements. Products are grouped by type of ingredient(s) tested and are listed alphabetically within each group. Seven products were selected by ConsumerLab.com and five others (each with an asterisk) are included for having passed the same evaluation through ConsumerLab.com's Voluntary Certification Program.

Shown for each product is the claimed amount of the tested ingredient and the daily serving size recommended on its label. Products listed as "Approved" met their label claims and ConsumerLab.com's quality criteria (see Passing Score). The full list of ingredients (including special dietary designations) is available for each product by clicking on the word "Ingredients" in the first column. Distinguishing points about the products are noted in the Comments column.

CONSUMERLAB.COM RESULTS FOR CHOLESTEROL-LOWERING SUPPLEMENTS: PHYTOSTEROLS AND POLICOSANOLS

Click on **S Price Check** beneath a product name to find a vendor that sells it. To find retailers that sell some of the listed products click here.

Phytosterol	Prod	lucts
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Product Name, Serving Size, and Suggested Daily Dose on Label Click on "Ingredients" for Full Listing	Company (Dist. = Distributor Mfd. = Manufacturer)	Labeled Amount of Sterol / Stanol and Apparent Form**	QUALITY APPROVAL STATUS APPROVED (Passed) or NOT APPROVED (Failed)	Contained Claimed Amount of Sterols and Did Not Exceed Conta- mination Limit for Lead	Disintegrated Properly (NA = Not Applicable)	Comments
Centrum Cardio (1 tablet, 2 per day) Ingredients \$ Price Check	Dist. by Wyeth Consumer Healthcare	800 mg sterols Free	APPROVED	✓	•	Sterols plus a multivitamin with very high vitamin B-12 (3333% of DV) (B-12 is not known to reduce cholesterol levels.)

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CholestaPRO (2 tablets, 2 per day) Ingredients	Dist. by Central Coast Nutraceuticals, Inc.	800 mg sterols Free	NOT APPROVED	/	Failed to disintegrate to release ingredient.	Sterols only. Improper dosing. Distributor fined for marketing tactics.
CholestOff (2 caplets, 4 per day)* Ingredients Price Check	Dist. by Nature Made Nutritional Products	1,800 mg sterols/ stanols Free	APPROVED	1	✓	Sterols/stanols only
Enzymatic Therapy Cholesterol Shield (1 tablet, 3 per day) Ingredients Price Check	Mfd. by Enzymatic Therapy, Inc.	1,200 mg sterols Free	APPROVED	•	✓ ·	Includes <u>pantethine</u> , which may also lower cholesterol.
Nature's Code Phytosterols 400 mg (1 caplet, 2 per day) Ingredients	Dist. by Health Ventures Partners	800 mg sterols Free	APPROVED	/	✓	Sterols only
TwinLab Cholesterol Success (2 tablets, 4 per day)* Ingredients Price Check	Mfd. by ISI Brands Inc.	1,800 mg sterols/ stanols Free	APPROVED	•	•	Sterols/stanols only
Vitamin Shoppe M.D. Select Dr. Ronald Hoffman Advanced Cholesterol Formula (2 veggie capsules, 4 per day)* Ingredients Price Check	Dist. by The Vitamin Shoppe	1,300 mg Free	APPROVED	•	•	Includes Sytrinol TM which may also lower cholesterol, and turmeric and olive fruit extract, both of which may prevent LDL oxidation.
Windmill Rx Premium Plant Sterol Cholesterol Control (1 caplet, 2 per day) Ingredients	Mfd. by Windmill Health Products	800 mg Free	APPROVED ¹	/	NA	Includes garlic that may help lower cholesterol and a tiny amount of policosanol (5 mg/2 pills).

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Product Name, Serving Size, and Suggested Daily Dose on Label Click on "Ingredients" for Full Listing	Company (Dist. = Distributor Mfd. = Manufacturer)	Labeled Amount of Policosanol per Daily Serving	QUALITY APPROVAL STATUS APPROVED (Passed) or NOT APPROVED (Failed)	Contained Claimed Amount of Policosanol and Did Not Exceed Conta- mination Limit for Lead	Disintegrated Properly (NA = Not Applicable)	Comments
Nature's Life Sun Food Energy Policosanol 23 mg (1 tablet, 1 per day) Ingredients \$ Price Check	Mfd. by NutraPure, Inc	23 mg	APPROVED	/	✓	Policosanol only.
NSI Nutraceutical Science Institute Policosanol featuring BioCosanol (1 capsule, 1 per day) Ingredients	Dist. by Nutraceutical Sciences Institute	20 mg	APPROVED	•	NA	Policosanol only.
Solgar Policosanol 20 mg (1 vegetarian capsule, 1 per day)* Ingredients \$ Price Check	Mfd. by Solgar Vitamin and Herb	20 mg	APPROVED	•	NA	Policosanol only.
Swanson Ultra Policosanol (1 capsule, 1 to 2 per day)* Ingredients \$ Price Check	Dist. by Swanson Health Products	20 to 40 mg	APPROVED	•	NA	Policosanol only.

¹ This product also listed policosanol, 2.5 mg per caplet. CL did not test the policosanol content due to the very low amount. NA = Not applicable

Unless otherwise noted, information about the products listed above is based on samples purchased by ConsumerLab.com (CL) for this Product Review. Manufacturers may change ingredients and label information at any time. So be sure to check labels carefully when evaluating the products you use or buy. If a product's ingredients differ from what is listed above, it may not be the same as what was tested.

For each product, the sample was composed of one or more products from a lot having an expiration date (if labeled) later than the date of testing. Because ingredients and labeling may vary from lot to lot and there may be a lack of consistency within lots, CL cannot assure that results for other samples will be the same as those listed above.

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^{*}Tested through CL's <u>Voluntary Certification Program</u> prior to, at time of, or after initial posting of this Product Review.

^{**}As most products did not indicate the sterol form (free or ester), forms shown above are assumptions based on amounts of free sterols found on testing by ConsumerLab.com.

The information contained in this report is based on the compilation and review of information from product labeling and analytic testing. CL applies what it believes to be the most appropriate testing methods and standards. The information in this report does not reflect the opinion or recommendation of CL, its officers or employees. CL cannot assure the accuracy of information provided to it by third parties. Liability to any person for any loss or damage caused by errors, omissions, or inaccuracies in this report is hereby disclaimed.

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ConsumerTips™:

What to Consider When Buying:

• Sterols: Although small amounts of plant sterols are present in the diet, larger amounts are needed to reduce cholesterol levels. Look for products that provide a minimum of 1.3 grams of total plant sterol esters (equivalent to about 800 mg free sterols) divided over two or more servings per day. In fact, according to the FDA, supplements and foods that provide at least this amount of sterols may reduce the risk of heart disease when part of a diet low in saturated fat and cholesterol. Successful clinical trials have also used doses up to 3 grams of total plant sterol esters or 1,800 mg of free sterols (Lau 2005; Vanstone 2002). Plant stanol esters may have the same effect, although at a slightly higher amount — 3.4 grams divided over two or more servings per day. A recent clinical study evaluated one of the products in this Review, *CholestOff*, which provides 1,800 mg daily of mixed free stanols and sterols divided into two servings taken with meals. Participants in the study, who had elevated LDL levels, were first put on a low-cholesterol diet (the "TLC Diet") for several weeks to establish baseline cholesterol levels. Taking *CholestOff* for six weeks, in addition to the ongoing diet, lowered LDL cholesterol from the baseline by about 4% and total cholesterol by about 3% (Maki, 2011). While these reductions were clinically significant, they are less dramatic than those seen in some other studies, possibly because the participants were already on a low-cholesterol diet.

If a product contains plant sterol esters, the sum of free beta-sitosterol, campesterol and stigmasterol should not be less than 62.5% of the total claimed amount.

• Policosanol: All positive studies have been conducted using policosanol from sugar cane; other forms of policosanol (such as from rice bran wax) differ in their composition and none have been found effective in studies; more recently, the efficacy of sugar cane policosanol has also been placed in doubt. Policosanol includes a variety of long-chain alcohols, such as octacosanol. A Cuban research group that has done most of the research on and marketing of sugarcane policosanol claims that you should look for products that contain no less than 60% (%wt/wt) octacosanol (although current specifications in the market are approximately 50 to 55%). In addition, they state that the sum of octacosanol, tetracosanol, hexacosanol, heptacosanol and nonacosanol should represent no less than 85% (%wt/wt). However, research conducted outside of Cuba on Cuban policosanol and other sugarcane policosanols with a similar profile have shown no significant benefit.

What to Consider When Using:

- **Sterols:** Plant sterols should be taken *with meals* in order to block cholesterol absorption. Reduction in cholesterol is typically seen within a few weeks, but the full effect can take about three months. If you use beta-sitosterol (a sterol) to treat symptoms of enlarged prostate, realize that, unlike sterols used for cholesterol-lowering that work in the gut, beta-sitosterol must be absorbed and should be taken on an *empty stomach* to increase its absorption.
- **Policosanol:** The typical recommended dose is 5-10 mg twice daily; however even this amount may not be effective, and only sugarcane policosanol has any supporting evidence for benefit, thought recent

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studies place this benefit in doubt.

Concerns and Cautions:

- Sterols, Stanols and their Esters: These substances are considered to be quite safe. There is some concern that they might inhibit absorption of beta-carotene, vitamin E and perhaps other fat-soluble vitamins (A and D) as well, so use of a nutritional supplement is recommended but should be taken at a different time than sterols and stanols.
- Policosanol: A range of side effects have been reported, including migraines, insomnia, sleepiness, irritability, dizziness, upset stomach, increased drinking, painful urination, weight loss, skin rash. According to the Cuban research group whose efficacy research has been placed in doubt, policosanol can inhibit platelet aggregation; nose and gum bleeding have been reported. Consequently, it should be used cautiously with anti-platelet or anti-coagulant drugs.

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