

PHYTOSTEROL COMPLEX

Product Education
www.newspirit.com



IS YOUR CHOLESTEROL TOO HIGH? THERE IS A NATURAL ALTERNATIVE.

According to the CDC, approximately 71 million American adults have elevated levels of LDL ('bad cholesterol'). High LDL cholesterol is one factor that may increase risk for heart disease. Heart disease is the leading cause of death in the U.S. and accounts for about 600,000 deaths each year according to the national Centers for Disease Control and Prevention. Other factors that raise the risk of heart disease include older age, diabetes, a family history of heart disease, high blood pressure, lack of exercise, obesity, or are a smoker. Often when all these factors are taken into considerations physicians may prescribe statin drugs. The use of statin drugs has increased sharply in the past several years and they are now among the most widely prescribed medicines in the U. S. According to the National Health and Nutrition Examination Survey 22% of Americans 45 years and older take a statin drug and as a class, statins and their related combination products generated \$16.9 billion in U. S. sales in 2012.

While they are quite popular, many people experience one or more of the following side effects:

- Headache
- Rash
- Diarrhea
- Difficulty Sleeping
- Drowsiness
- Bloating or gas
- Nausea or vomiting
- Constipation
- Dizziness
- Flushing of the skin
- Abdominal cramping or pain
- Muscle aches, tenderness or weakness (myalgia)

BENEFITS

- Helps reduce LDL (bad cholesterol) levels.
- Niacin increases HDL (good cholesterol) level
- Plant sterols reduce cholesterol absorption, lowering heart disease risk.
- Niacin benefits the nervous system, digestion, and skin.
- A natural option for those who can't tolerate statins.

STATIN DRUG WARNING

Statins also carry warnings that memory loss, mental confusion, high blood sugar, and type 2 diabetes are possible effects. It's important to remember that statins may also interact with other medications you take. If you experience any unexplained joint or muscle pain, tenderness, or weakness while taking statins, you should call your doctor immediately. Pregnant women or those with active or chronic liver disease should not use statins.†

Plant Sterols as a Natural Alternative And/or Complementary Product

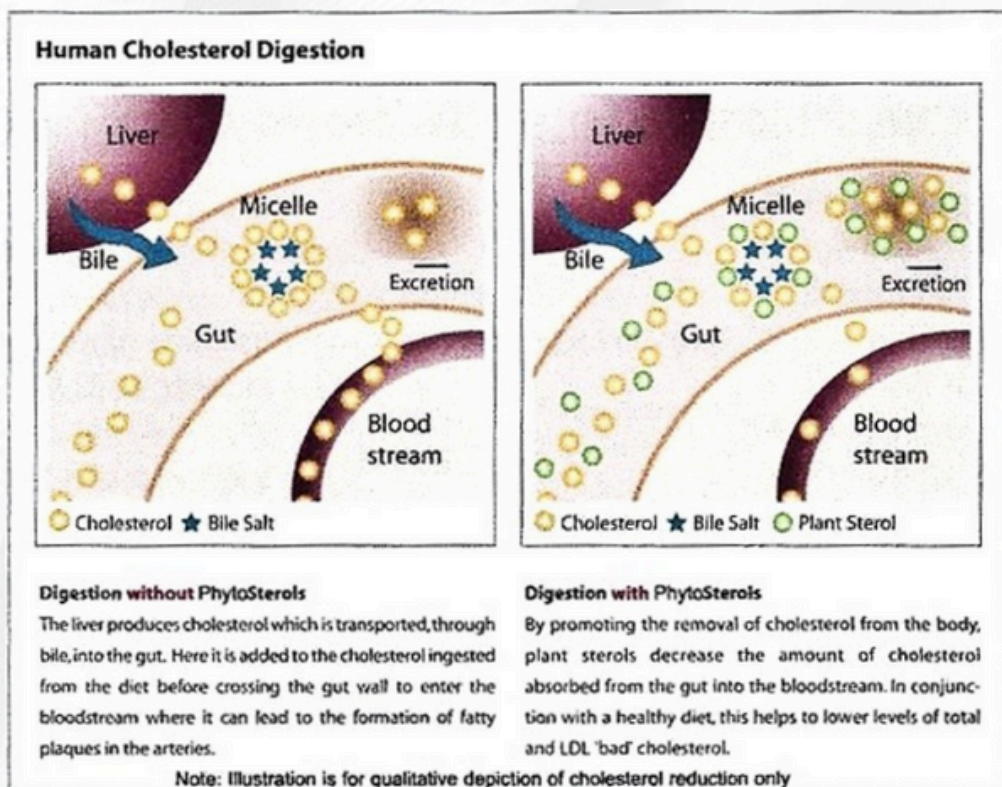
Plant sterols/stanols (Phytosterols) are naturally found in fruits, vegetables, nuts, seeds, cereals, and legumes, whereas cholesterol is derived from animals. Phytosterols naturally interfere with the intestinal absorption of cholesterol, thereby lowering cholesterol levels. Certain vegetable spreads found in the grocery store also contain plant sterols/stanols that can lower cholesterol and are beneficial to long-term health—especially when used to replace butter or margarine.

Foods that have a favorable impact on blood cholesterol:

- Olive Oil, Beans, Nuts (Almonds), Legumes
- Cold water fish - (Salmon Omega 3s) lowers triglycerides
- Red wine - raises the good (HDL)
- Cinnamon - lowers the bad (LDL) cholesterol
- Whole grains (Quinoa, Brown Rice, Bulgur, Wheat Germ)
- Soluble fiber □ Soybeans
- Plant sterol margarine
- Oatmeal
- A normal human diet may contain 160-400 mg. of stanols/sterols BASF Nutrition & Health
- New Spirit Naturals phytosterols are derived from sunflower and are NON-GMO

Plant Sterols - How do they work?

Plant sterols reduce the absorption of cholesterol by 30 to 60%.



Plant Sterols & sterol esters Recommendations

Numerous health organisations and institutions recommend the supplementation of 2 g plant sterols daily as a safe cholesterol lowering therapy, e.g.

- The World Heart Federation (WHF)
- The American Heart Association (AHA)
- The US National Heart, Lung and Blood Institute (NHLBI)
- The German Association for Nutritional Medicine & Dietetics (VFED)
- The Australian Heart Foundation
- The British Heart Foundation
- Sociedad Argentina de Cardiología



US FDA Approved Health Claim (2000)

"Foods containing at least 0.65g per serving of vegetable oil sterol esters (or 0.4g sterols), eaten twice a day with meals for a daily total intake of at least 1.3g (or 0.8g sterols), as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease."

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfdr/CFRSearch.cfm?r=101.83>

The following statements can also be made*:

- Proven to help reduce cholesterol
- Proven to help reduce total cholesterol
- Proven to help reduce LDL cholesterol
- May help to lower cholesterol naturally
- May help to lower cholesterol

* The health claim must appear nearby these statements



Federal Register

Friday,
September 8, 2000

Part III

Department of
Health and Human
Services

Food and Drug Administration

21 CFR Part 101
Food Labeling: Health Claims: Plant
Sterol/Sterol Esters and Coronary Heart
Disease: Sterols Final Rule

INGREDIENTS

Nicotinic Acid (Niacin)

- A form of Vitamin B3
- 50 mg. per serving
- Niacin is reported to reduce cholesterol levels and lower the risk of heart disease. In addition, it helps increase HDL (good cholesterol).
- Niacin is involved in the metabolism of carbohydrates, proteins and fat and the generation of energy in food.

Red Yeast Rice

- 130 mgs. per serving
- Red yeast rice is a substance extracted from rice that has been fermented with a special type of yeast. It has been used for centuries in China and Asian countries as a traditional medicine.
- Red yeast rice is reported to contain several ingredients that may help reduce cholesterol levels. These include a number of monacolins, sterols, isoflavones and monounsaturated fatty acids.
- The benefits of red yeast rice extend beyond controlling cholesterol. Additional benefits include reducing inflammation, blood sugar support, blood pressure support and helping with metabolic syndrome. Other reports show that it can help stimulate bone growth.
- Some studies show that red yeast rice can reduce total cholesterol by 15% and LDL (bad) cholesterol by up to 21% over a period of 3 months.

Results

Overall findings indicate a 15.5% LDL-Cholesterol reduction* compared to the control group. Low fat diet alone accounted for an 8.9% LDL-Cholesterol reduction, hence a “prudent” Western diet plus phytosterols brought about a decrease in total cholesterol in the order of 24.4% from baseline measurement.

*Source- Jones, et. al. American Journal of Clinical Nutrition (1999)

The use of a dietary supplement containing sterols/stanols in a convenient capsule supplement (in concentrated form) may be a more convenient option that may increase the compliance during long-term use. Capsules are particularly convenient when compared to the major significant dietary changes required over long periods of time to increase the incorporation of phytosterols-containing foods. Compliance to a therapeutic lifestyle change (TLC) is necessary when the goal is to reduce LDL-C levels to affect a decrease in the risk of coronary heart disease (Maki et al., 2013).

Based on the scientific evidence available New Spirit Naturals, Inc. is introducing a new product, Phytosterols Complex in capsules form to help one obtain this necessary nutrient in the diet. One serving of New Spirit Naturals' Softgel Phytosterols Complex. (with Beta Sitosterols, Campesterol, and Stigmasterol) contains an equivalent of 1000 mg of phytosterol complex (equivalent to 900mg's. plant sterols)One bottle contains 60 capsules.

ADDITIONAL BENEFITS ON CONSUMING PHYTOSTEROLS

Anti-Atherogenicity Activity

In vitro studies have shown that plant sterols are effective in preventing hyperproliferation of vascular smooth muscle cell that play a role in Atherosclerosis development.

Source: Awad AB, Smith AJ, Fink CS, Plant sterols regulate Rat vascular smooth muscle cell growth and prostacyclin release in culture.

Source: Prostaglandins Leukot Essential Fatty Acids 2001;64:323-330

Anti Cancer Activity

Compared to Cholesterol, B-Sitosterol caused a 24% decrease in cell growth and a 4-fold increase in apoptins. Plant sterol-fed mice had a 33% smaller tumor size and 20% less metastases in lymph nodes and lungs than cholesterol-fed mice. This finding implied the possibility that plant sterols may retard the growth and spread of breast cancer cells. In addition to retarding the growth of breast cancer cells, there is some evidence that plant sterols can affect the development of prostate cancer.

Source: Awad AB, Smith AJ, Fink CS, Plant sterols regulate Rat vascular smooth muscle cell growth and prostacyclin release in culture.

Source: Prostaglandins Leukot Essential Fatty Acids 2001;64:323-330

Urinary Symptoms – Prostate

In a Meta-analysis, 519 men were studied in 4 randomized, placebo controlled, double blind trials. B-sitosterol improved urinary symptom scores and flow measures. There is some evidence that plant sterols can affect the development of prostate cancer.

Source: Wilt T, Ishania, MacDonald R, Stark G, Mulrow C, Lay, Beta-Sisterols for benign Prostate hyperplasia. Cochrane database syst-2. RCU 2000 CD001043 Review

Suggested Use:

Adults take two (2) capsules twice daily with your two largest meals of the day

References:

1. Diet, Nutrition Intake, and Metabolism in populations at high and low risk for colon cancer. The American Journal of Clinical Nutrition 40:1984 pp927-930
2. Raicht RF, Cohen B1, Iazzini ED et al. Protective effects of plant sterols against chemically induced colon tumors in rats. Cancer Res 1980;40:403-5
3. Deschner EE, Cohen B1, Raicht RF. Kinetics of the protective effects of B-sitosterol against MNU induced colonic neoplasia. J cancer Res, Clin oncol 1982;103:49-54
4. Maki, K.C. Lanless
5. McKenny J Jenks, Shneyves, E. Brook
6. Beta-Sitosterol, by Stephen B. Strum, MD, FACP, and William Faloan, Life Extension Magazine, June 2005.



The product label for New Spirit Naturals Phytosterol Complex features a background image of a sun rising over a field of sunflowers. The label is divided into several sections: a top banner with the company logo and name, a central product title, a left sidebar with a disclaimer and company information, a right sidebar with supplement facts and directions, and a bottom banner with the product type and count.

NEW SPIRIT NATURALS

Phytosterol Complex

WITH RED RICE YEAST & NIACIN

Dietary Supplement | 60 Capsules

Supplement Facts:

	Amt. Per Serving	%DV*
Phytosterol Complex 90% (Beta Sitosterol, Campesterol, Stigmasterol)	1000mg	†
Niacin (Nicotinic Acid)	50mg	320%
Red Rice Yeast (Monascus Purpureus Went, seed)	130mg	†

Other ingredients: Palm Oil Powder (Eleasis Guineensis), Vegetable Capsule

* Percent Daily Values are based on a 2,000 calorie diet.
† Daily value (DV) not established.

Directions: Adults take two capsules (one serving) daily with meals.
Warning: If you are pregnant, nursing, taking any medications or have any medical condition, consult your doctor before use. Discontinue use and consult your doctor if any adverse reactions occur.
KEEP OUT OF REACH OF CHILDREN. Keep tightly closed in a cool dry place.

Left Sidebar Text:
Foods containing at least 0.4 g per serving of plant sterols, eaten twice a day with meals for a daily total intake of at least 0.8 g as part of a diet low in saturated fat and cholesterol, may reduce the risk of heart disease. Two capsules will provide 0.9 g of phytosterols (plant sterols).
† Made in a facility that manufactures products using soybeans, milk, wheat, fish, shellfish and tree nuts.
Nutrition With Intention®
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GMP
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#3001 v2

†These statements have not been evaluated by the FDA. Information contained in this bulletin is for informational purposes only and is not intended to diagnose, treat, cure, or prevent any disease. In all cases, it is recommended that you consult with your healthcare professional before initiating a supplement program.