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Biotix

CHOLESTEROLBIOTIX

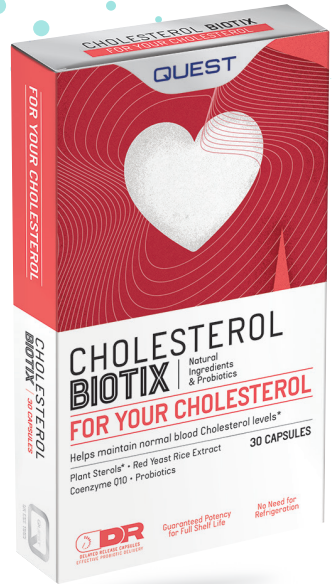
A unique formulation of potent ingredients to reduce cholesterol levels.

Nutritional Information

One capsule provides:

| | |
|--|---------|
| Plant sterols (phytosterols) | 400 mg |
| Concentrated red yeast rice extract (Providing 1.45mg monacolin-K) | 48.5 mg |
| Coenzyme Q10 | 10 mg |
| Lactobacilli Culture (Providing 1 billion (1 x 10 ⁹) L.rhamnosus & L.bulgaricus) | 12 mg |

Take two capsules daily, with or after a meal.



SUMMARY

- Contains three natural ingredients working synergistically to reduce cholesterol levels.
- Red yeast rice (monacolin-K) inhibits production of cholesterol.
- Plant sterols (phytosterols) inhibit the absorption of cholesterol.
- Lactobacilli probiotic bacteria help in the metabolism and elimination of cholesterol.
- CoQ10 is included as a supporting ingredient.

DESCRIPTION

CholesterolBiotix is a unique formulation containing three natural-based cholesterol-lowering ingredients: plant sterols (phytosterols); red yeast rice extract (monascus purpureus), and lactobacilli probiotic bacteria. All three ingredients work in different ways to help support cholesterol levels naturally. Plant sterols inhibit the intestinal absorption of cholesterol; red yeast rice extract (containing monacolin-k) reduces the production of cholesterol by the body; and lactobacilli bacteria help the liver excrete cholesterol from the body. The formulation also includes CoQ10, which is recommended for patients on cholesterol lowering statins.

HOW DOES CHOLESTEROLBIOTIX HELP CONTROL CHOLESTEROL LEVELS?

Plant Sterols

An intake of plant sterols can significantly reduce elevated serum levels of LDL cholesterol. The cholesterol-lowering effect of plant sterols is caused by their inhibition of intestinal cholesterol absorption.¹

A comprehensive 2009 meta-analysis of 84 clinical studies observed that plant sterol intake resulted in an average decrease of 8.8% in LDL cholesterol levels between 8 to 12 weeks. Using a dose-response analysis, the review also demonstrated that an intake of 2000mg daily from the diet and supplements would result in a 9% decrease in LDL cholesterol.

In 7 of the studies, daily doses of 800mg – 1000mg of plant sterols observed statistically significant reductions in LDL cholesterol.²

The European Food Safety Authority (EFSA) has also provided a positive scientific opinion on the cholesterol-lowering health claims related to plant sterol intake, and have stated that the beneficial effect is obtained with a moderate daily intake of at least 800mg.³

Red Yeast Rice (Monacolin-K)

Red yeast rice extract is the product of yeast (*monascus purpureus*) fermented with rice. It contains several compounds collectively known as monacolins, including monacolin-K, which is formed during the fermentation process.

Monacolin-K is a potent inhibitor of HMG-CoA reductase, an enzyme that triggers cholesterol production in the body. As a result, monacolin-K in red yeast rice extract can inhibit the production of cholesterol in the body.

There are several clinical trials assessing the efficacy of monacolin-K in red yeast rice extract in reducing cholesterol levels.^{4,13} Most recently, a 2013 randomised double-blind placebo-controlled trial using 10.2mg monacolin-K daily observed a 22% reduction in LDL cholesterol after 8 weeks.⁵ The European Food Safety Authority (EFSA) has also provided a positive scientific opinion on the cholesterol-lowering health claims related to monacolin-K from red yeast rice.⁶ The opinion was based on two double blind, placebo-controlled human intervention studies, which demonstrated a significant reduction in total cholesterol concentrations in the red yeast rice treatment groups compared to the placebo groups. One of these trials observed a 27.7% reduction in LDL cholesterol in patients taking 11.5mg monacolin-K daily for 8 weeks.^{7, 8}

CholesterolBiotix is a natural alternative to synthetic statin (lipid-lowering) drugs. Monacolin-K has the same chemical structure as lovastatin, a widely marketed prescription statin medication. There is some data to suggest that red yeast rice (containing monacolin-K) products are a viable alternative for patients that have discontinued statin drugs due to myalgia or myopathy (muscle pains and weakness) side effects. In one clinical trial, red yeast rice extract was successfully trialed in 62 patients with a history of discontinuation of statins due to myalgia, and observed a 21% reduction in LDL cholesterol after 24 weeks.⁹

Lactobacilli Probiotic Bacteria

There is emerging research to suggest that lactobacilli probiotic bacteria have cholesterol-lowering properties through their ability to remove cholesterol within the body.¹⁰ A recent meta analysis of 33 clinical trials concluded that probiotics were a useful primary prevention of high cholesterol.¹²

Lactobacilli strains, belong to a group of bacteria called bile salt hydrolase active bacteria. *L. rhamnosus* and *L. bulgaricus* are some of these studied strains and metabolise bile in the gut^{14,15}. After the release and use of bile, the body usually conserves energy and reabsorbs and recycles it. However, since *L. rhamnosus* and *L. bulgaricus* metabolises bile, it cannot be reused, meaning the body relies on its cholesterol stores to make fresh bile.

It is suggested that they include the assimilation of cholesterol by the probiotic bacteria, incorporation of cholesterol into the cellular membranes of probiotic bacteria during growth, cholesterol binding to the probiotic bacterial cell wall, the conversion of cholesterol to coprostanol by probiotic bacteria, and the enzymatic deconjugation of bile.¹¹

Combinations study

A randomized, double-blinded, placebo-controlled clinical trial was conducted involving 39 adults with high total cholesterol. The study looked at the effect of monacolin K combined with probiotic bacteria supplementation for 12 weeks. The test group achieved a statistically significant greater reduction in LDL cholesterol and total cholesterol in the intervention group compared to the placebo group. No adverse effects were reported¹⁸.

WHY DOES CHOLESTEROLBIOTIX CONTAIN COENZYME Q10?

CoQ10 supplementation is recommended for patients on cholesterol lowering statin medications which lower CoQ10 levels in the body, increasing the risk of adverse effects such as pain and muscle weakness.

Monacolin-K, contained in red yeast rice extract, has the same chemical structure as lovastatin. Therefore, coenzyme Q10 is included in the formulation of CholesterolBiotix to counteract any negative reduction in coenzyme Q10 levels from red yeast rice extract supplementation.

RED YEAST RICE FOR STATIN INTOLERANT INDIVIDUALS

Research has been conducted on the use of red yeast rice in statin intolerant individuals. Statins can sometimes have unpleasant side effects for some patients, the main side effect being myalgia. One study looked at 62 patients with dyslipidaemia, who has previously stopped statin therapy due to myalgias. It concluded that red yeast rice along with lifestyle changes decreases LDL cholesterol without increasing creatinine phosphokinase (CPK) or pain levels and may be a suitable intervention for patients with dyslipidaemia who cannot tolerate statins¹⁶.

Another study compared red yeast rice and pravastatin in 43 patients unable to tolerate other statins and with a history of statin discontinuation. Red yeast rice was well tolerated and a comparable reduction in LDL cholesterol was noted¹⁷.

HOW SHOULD CHOLESTEROLBIOTIX BE TAKEN?

Two capsules daily with or after a meal (European countries)*. Two to three capsules daily with or after a meal (non-European countries).

*Products containing more than 10mg of monacolin-K are classified as pharmaceutical in some European markets. As a result, to maintain food supplement status for European countries, CholesterolBiotix dosage is recommended at 2 capsules per day within Europe.

ARE THERE ANY PRECAUTIONS BEFORE OR WHILE TAKING CHOLESTEROLBIOTIX?

This product is intended exclusively for people wanting to lower their cholesterol and is not suitable for:

- Pregnant or breastfeeding women;
- Children below 18 years old;
- Adults over 70 years old;
- Individuals with liver disease or at risk of liver disease, as red yeast rice may impair liver function.
- Individuals with acute infections, kidney disease, or who have had an organ transplant.

CholesterolBiotix should not be taken together with any other lipid-lowering statin medication without prior consultation with a healthcare professional. Additionally, a healthcare professional should be consulted before taking CholesterolBiotix whilst taking any other medication. The total dietary intake of phytosterols from food supplements should not exceed 3g per day. It is recommended not to consume more than 3mg of monacolins from red yeast rice extract daily¹⁹.

THE ADVANTAGE OF DRCAPS™

DRcaps are designed to delay the release of probiotic bacteria, protecting the probiotics from stomach acidity and allowing the probiotics to be most effective where they need to be - directly in the intestine.



Images of DRcaps disintegration performance in human subject*

TIME

30 mins

STOMACH

DRcaps stay intact at 30 mins

Standard HPMC caps release before 30 mins

105 mins

SMALL INTESTINE

DRcaps release between 105-120 mins

Subject 003

Time = 0 min

DRcaps capsule reaches the stomach intact

Subject 003

Time = 105 min

DRcaps capsule has left the stomach and release its contents in the intestine

*Subject consumed light breakfast 30 minutes prior to dosing DRcaps containing 300mg of lactose, 10mg of which was radiolabelled to allow anterior and posterior images taken every 5 minutes after dosing.

FEATURES

- Combines four potent nutrients in a unique specialist formula
- With DRcaps, a unique delayed release capsule shell that protects sensitive bacteria from stomach acid
- Lyophilised, encapsulated and individually sealed to enhance stability
- Refrigeration is optional.

HEALTH NEEDS



HEART AND CIRCULATION

SCIENTIFIC REFERENCES

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