

CholesterX



FUNCTIONAL
NUTRIENTS®

Clinical Applications

- Supports Healthy Blood Lipid Levels*
- Promotes Healthy Cholesterol Levels Already Within Normal Range*
- Supports Cardiovascular Health*

*CholesterX features a patented extract produced by fermenting non-GMO rice with *Monascus purpureus* (red yeast). Extract of red yeast rice helps promote healthy blood lipid and cholesterol levels already within normal range. CholesterX is ideal for individuals seeking support for cardiovascular health and is third-party tested to confirm monacolin K and citrinin are not detected.**

All Personalized Medical Solutions Formulas Meet or Exceed cGMP Quality Standards

Discussion

Red yeast rice (RYR) has a rich history of traditional medicinal use in East Asia. Its first recorded use was documented during the Tang Dynasty (AD 618-907). It is produced by the fermentation of cooked rice kernels with a strain of *Monascus purpureus* yeast. In China and neighboring Asian countries, RYR is used as a food preservative, flavor enhancer, and coloring agent. It has long been utilized in traditional Chinese medicine for a wide range of ailments, including indigestion and blood circulation stasis. However, it is most well-known for its biological properties related to support of cardiovascular health.*^[1]

Monacolin K

Red yeast rice is comprised of a wide variety of chemical constituents, including pigments, tannins, phytochemicals such as sterols and isoflavones, and monounsaturated fatty acids. Monacolin K is the most widely studied bioactive component of RYR, and much of the hypolipidemic effect benefitting cardiovascular health has been attributed to it. Monacolin K has the same mechanism of action as an active ingredient in statins, drugs which lower blood cholesterol levels by inhibiting the biosynthesis pathway of cholesterol in the liver.^[2,3] In vitro, animal, and human studies have shown a cause and effect relationship between the consumption of monacolin K from RYR and the maintenance of cholesterol levels within a normal range, providing the European Food Safety Authority (EFSA) with adequate scientific substantiation to warrant a health claim for monacolin K.^[4] However, in 1998, the FDA had already classified RYR products containing more than a trace amount of monacolin K as unapproved new drugs. Since then, sellers have been issued warnings that it is against the law to market these products as dietary supplements in the United States. Additionally, RYR with monacolin K has the potential to incur the same types of side effects as statins, most notably myopathy, rhabdomyolysis, and liver toxicity.*^[5]

Despite speculation that RYR without monacolin K may not have the same effect on blood cholesterol levels, studies have shown that other metabolites of the *Monascus* species also possess hypolipidemic functions. Monascin and ankaflavin are yellow pigments from *M purpureus* that support healthy inflammatory activity^[3] and have been studied for their potential contribution to cardiovascular health. In a 6-week study, hamsters were fed a high-cholesterol diet and were orally administered equal dosages of monascin, ankaflavin, and monacolin K to compare the hypolipidemic and anti-atherosclerotic effects and potential side effects of these compounds. Results indicated that monascin and ankaflavin had similar activity to monacolin K in providing a significant reduction of total cholesterol (TC), triglyceride (TG), and low-density lipoprotein cholesterol (LDL-C) levels. Regarding the potential for side effects, monacolin K also raised elevated creatine phosphokinase activity, which was highly correlated with rhabdomyolysis development, while monascin and ankaflavin did not induce this side effect.*^[6]

Citrinin

Citrinin is a secondary metabolite found in food and feed that is produced by several fungal species including *M purpureus*. This mycotoxin can develop if the process of culturing RYR is not carefully controlled. Citrinin has been shown to cause kidney damage and disrupt liver function. In a 2011 analysis of red yeast rice products sold as dietary supplements, four of 11 products were found to contain this contaminant.^[1,5] Personalized Medical Solutions's Red Yeast Rice formula is citrinin-free.*

Ankascin® 568-R

Ankascin 568-R is an extract of fermented *M purpureus* that contains the active compounds monascin (2.8%) and ankaflavin (0.9%) with no monacolin K or citrinin. The manufacturer of Ankascin 568-R holds 28 patents worldwide, and the ingredient has passed multiple safety assessments including FDA approval as a new dietary ingredient.^[7]

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***These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.**

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Report any adverse reactions to 425-391-3376

CholesterX



Supplement Facts

Serving Size: 2 Capsules
Servings Per Container: 30

	Amount Per Serving	%Daily Value
Red Yeast Rice Extract (<i>Monascus purpureus</i>)(2.8% monascin, 0.9% ankaflavin) ^{S1}	110 mg	**

** Daily Value not established.

Other Ingredients: Dicalcium phosphate dihydrate, capsule (hypromellose and water), ascorbyl palmitate, and silica.

S1. ANKASCIN® 568-R is a registered trademark of SunWay Biotech Co., LTD.

Directions

Take two capsules daily, or use as directed by your healthcare professional.

Consult your healthcare professional prior to use. Individuals taking medication should discuss potential interactions with their healthcare professional. Not intended for use if you are pregnant or lactating. Do not use if tamper seal is damaged.

In a randomized, double-blind, placebo-controlled trial, subjects (N = 21) with a clinical diagnosis of hypertension were given two capsules of Ankascin 568-R/day containing 110 mg of RYR extract with 3 mg of monascin and 1.5 mg of ankaflavin per capsule for 8 weeks. Subjects in the test group had a significantly reduced systolic and diastolic blood pressure following 4 weeks of administration, and results were maintained until the end of the 8-week period. Additionally, the treatment group demonstrated a significant improvement in serum lipid profile with reduced levels of TC, TG, and LDL-C and no significant rhabdomyolysis or impairment of the metabolic or physiological functions of the liver or kidney.*^[2]

In another randomized, double-blind, placebo-controlled trial, subjects (N = 40) with borderline elevated cholesterol were given 110 mg Ankascin 568-R/day for an 8-week duration. A significant reduction was shown in serum cholesterol (11.9%) and LDL-C (19%) in as little as 4 weeks. In a 4-week washout period following the treatment phase, levels reverted to baseline for both TC and LDL-C.*^[3]

An additional randomized, double-blind, placebo-controlled study explored the effect of Ankascin 568-R on blood glucose regulation. Subjects (N = 39) with elevated fasting glucose and HbA1c levels were given 220 mg of Ankascin 568-R daily for 12 weeks. The results showed a significant reduction in serum blood glucose as well as TC and LDL-C levels in test group subjects after 6 weeks. The authors noted Ankascin 568-R as a potentially useful ingredient for the regulation of blood glucose and the support of cardiovascular health.*^[6]

CholesterolX

offers 110 mg of Ankascin 568-R red yeast rice extract per two capsules daily. This formula does not contain monacolin K or citrinin and is ideal for individuals seeking dietary supplement support for cardiovascular health.*

Formulated To Exclude

Wheat, gluten, soy, animal and dairy products, fish, shellfish, peanuts, tree nuts, egg, ingredients derived from genetically modified organisms (GMOs), artificial colors, artificial sweeteners, and artificial preservatives.

References

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7. ANKASCIN® 568-R. Sunway Biotech Co., LTD.; 2017:1-15. Accessed February 4, 2021. <https://sunway.cc/en/white-paper/ef%bc%8dthe-ankascin-568-r-safe-effective-and-approved-red-yeast-rice-extract/>
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