



Update on **Red Yeast Rice**

By Raina Roeder, RD

Remember back when red yeast rice was featured as an herb blurb? Since that information was sent out, the U.S. Food and Drug Administration (FDA) has initiated warnings for consumers about these products. Certain red yeast rice products, used most often to lower cholesterol, may not be as safe as once advertised.

Please read the warning below from the FDA. If you or anyone you know or care about is taking a red yeast rice supplement, please inform them of these warnings. (Below the FDA News warning is a copy of the previous herb blurb about red yeast rice that was sent out in April, 2007.)

FDA News

FOR IMMEDIATE RELEASE
August 9, 2007

Media Inquiries:

Catherine McDermott, 301-827-6242

Consumer Inquiries:

888-INFO-FDA

FDA Warns Consumers to Avoid Red Yeast Rice Products Promoted on Internet as Treatments for High Cholesterol **Products found to contain unauthorized drug**

The U.S. Food and Drug Administration is warning consumers not to buy or eat three red yeast rice products promoted and sold on Web sites. The products may contain an unauthorized drug that could be harmful to health. The products are promoted as dietary supplements for treating high cholesterol.

The potentially harmful products are: Red Yeast Rice and Red Yeast Rice/Policosonal Complex, sold by Swanson Healthcare Products, Inc. and manufactured by Nature's Value Inc. and Kabco Inc., respectively; and Cholestrix, sold by Sunburst Biorganics. FDA testing revealed the products contain lovastatin, the active pharmaceutical ingredient in Mevacor, a prescription drug approved for marketing in the United States as a treatment for high cholesterol.

"This risk is even more serious because consumers may not know the side effects associated with lovastatin and the fact that it can adversely interact with other medications," said Steven Galson, M.D., M.P.H., director of FDA's Center for Drug Evaluation and Research.

These red yeast rice products are a threat to health because the possibility exists that lovastatin can cause severe muscle problems leading to kidney impairment. This risk is greater in patients who take higher doses of lovastatin or who take lovastatin and other medicines that increase the risk of muscle adverse reactions. These medicines include the antidepressant nefazodone,

certain antibiotics, drugs used to treat fungal infections and HIV infections, and other cholesterol-lowering medications.

FDA has issued warning letters advising Swanson and Sunburst Biorganics to stop promoting and selling the products. Companies that do not resolve violations in FDA warning letters risk enforcement actions, such as an injunction against continuing violations and a seizure of illegal products.

The FDA warning letters state that the products Red Yeast Rice, Red Yeast Rice/Policosonal Complex, and Cholestrix, sold on the firm's websites, are unapproved new drugs that are marketed in violation of the Federal Food, Drug, and Cosmetic Act. The warning letters are available on FDA's Web site: www.accessdata.fda.gov/scripts/wlcfm/recentfiles.cfm.

FDA advises consumers who use any red yeast rice product to consult their health care provider if they experience problems that may be due to the product.

Report adverse events related to these products to MedWatch, the FDA's voluntary reporting program: www.fda.gov/medwatch/report.htm; 800-332-1088; Fax: 800-332-0178; and MedWatch, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD, 20852-9787.



Red Yeast Rice

Monascus purpureus

Julie Haase, RD, CD

Also Known As

Trade names: Cholesterol Management (Reese Pharmaceuticals), Cholestin (Pharmanex), Cholesterol (Nutura), Cholestesure (Natrol)

Other Names: Chinese red yeast rice, *Monascus purpureus*-fermented rice, Red leaven Red koji, Anka, Ang-kak, Ankak, Angquac, Beni-koji, Beni-Jiuqu, Aga-Jiuqu, Aka-koji, Xeuzhikang, Hung-chu, hongqu

What is it?

Red yeast rice, native to China, is a fermentation product of rice with strains of the yeast *Monascus purpureus*. It is ground into a fine powder form, called Zhi Tai, for various uses (listed below).

The product is actually quite complex, containing the following compounds: starch, fatty acids, phytosterols, isoflavones, trace elements (selenium, aluminum, calcium, iron, manganese, magnesium, copper and silver), protein, moisture, ash, phosphorus, and several compounds called monacolins. Monacolins are the most-studied component – specifically monacolin K, which has potent HMG CoA reductase activity. This is the same component found in cholesterol-lowering medications, such as lovastatin.

Uses

Traditional Chinese medicine has used red yeast rice for over a millennium to treat indigestion, diarrhea and improve blood circulation. Red yeast rice is also a flavor enhancer, food preservative and a Taiwanese rice-wine alcoholic beverage base.

It wasn't until the last decade that red yeast rice was used as a dietary supplement in the United States. As a supplement, it is primarily used to lower cholesterol and lower triglycerides.

How does it work?

The monacolins in red yeast rice act as a HMG CoA reductase inhibitor. This reduces the amount of cholesterol made by the body. Monacolins are the same component found in the prescription medications lovastatin, Zocor, Pravachol and Lipitor. In fact, red yeast rice is so similar to these medications that the FDA argued it is not a dietary supplement, but an unapproved drug. Currently, red yeast rice is still available as a nutritional supplement.

Although the monacolins are known HMG CoA reductase inhibitors, red yeast rice seems to be more potent than monacolins in prescription medications. For reasons

not understood, a 7.2 mg dose of lovastatin from red yeast rice may further decrease cholesterol than 10-40 mg prescription lovastatin. More research is needed to understand this better.

Research

Research on red yeast rice is ongoing, and results are limited to short-term studies. Recently, a multi-center study looked at 502 patients with hyperlipidemia over eight weeks. The study group took 600 mg red yeast rice twice daily while controls took a placebo. The group taking red yeast rice had lower LDL (“bad” cholesterol) and triglycerides, and increased HDL (“good” cholesterol).

Another double blind placebo controlled study of 83 pts with high cholesterol took either a placebo or 2,400 mg of a red rice yeast supplement. The group taking the red rice yeast had significant improvements in their total cholesterol and LDL and little change in their HDL over weight weeks.

However, a 2001 study showed that there can be a large variance in the monacolin content of commercially available red yeast rice. The range of monacolin content varied from 0%-0.58%. This study also showed that 7 of the 9 products studied contained citrinin, a toxic byproduct of fermentation.

Safety

Side effects: heartburn, gas, dizziness

Red Yeast Rice may interact with the same medications and supplements as lovastatin, including the following:

DRUGS: azole antifungals, cyclosporine, fibrates, gemfibrozil, macrolide antibiotics, neefazodone, protease inhibitors, statins (lovastatin, pravastatin) and warfarin.

SUPPLEMENTS: nicotinic acid, milk thistle, St. John’s Wort, Niacin, Vitamin A, Coenzyme Q10, guggul, fish oils, astaxanthin, zinc

FOOD: grapefruit juice

Contraindications:

- Contraindicated in people who have a hypersensitivity to rice or yeast
- Not recommended for people with liver disease or with unexplained transaminase elevations. Use with caution if you routinely use alcoholic beverages (more than one to two drinks daily).
- Not recommended for women who are pregnant, nursing or may become pregnant
- Side effect of weakness, unexplained muscle pain or tenderness may indicate myopathy, and these symptoms should be reported to your doctor

Dosage

1,200 mg - 2,400 mg, taken in divided doses (ie 400 mg, three times daily). Red Yeast Rice is usually supplied in 400 or 600 mg capsules. It is best absorbed with meals.

Monitoring

Liver tests should be checked before starting, at six and 12 weeks of using red yeast rice, and periodically as use is continued.

The Bottom Line

Red yeast rice may be beneficial in lowering total cholesterol by decreasing LDL synthesis. However, further research is needed to make final recommendations on safety and efficacy. Let your doctor know if you take red yeast rice or are thinking of taking red yeast rice.

It is important to remember that dietary supplements are not regulated U.S. Food and Drug Administration. Therefore, the amount of the active ingredient could vary from one supplement preparation to another. Always let your doctor know if you take a dietary supplement.

References:

PDR Health, www.pdrhealth.com

UpToDate @ www.utdol.com

Medline Plus www.nlm.nih.gov

(Photo from: <http://www.nlm.nih.gov/medlineplus/druginfo/natural/patient-redyeast.html>)

Memorial Sloan-Kettering Cancer Center www.mskcc.org

MD Anderson Cancer Center www.mdanderson.org