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## FROM: The Doctors' Desk

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Red Yeast Rice: Is it a reasonable alternative to statins to lower cholesterol or a risky unregulated natural substance?

Some patients are attracted to idea of lowering their cholesterol with natural methods. This includes a prudent diet, regular exercise and taking dietary supplements like red yeast rice (RYR). Red yeast rice is marketed as a natural dietary supplement to reduce cholesterol. It has been used in Chinese cooking and medicine for centuries. The first documented use of red yeast rice was in the Tang Dynasty in 800 A.D. An ancient Chinese pharmacopoeia recommended using red yeast rice for the treatment of indigestion, diarrhea, blood circulation and spleen and stomach problems.

Red yeast rice is made by fermenting a type of red yeast (Monascus purpureus) over rice. The process produces compounds called monacolins that lower cholesterol. One of these compounds is monacolin K which is chemically very similar to the first statin discovered for lowering cholesterol called mevastatin which itself is naturally produced by Penicillium citrinum. To enhance the potency in lowering cholesterol with a low side-effect profile, a similar but slightly different chemical was isolated from Aspergillus terreus and Monascus ruber called lovastatin. After approval by the FDA in 1987, this naturally fermented chemical was marketed as Mevacor by Merck and forever changed the face of preventive cardiac care. Monacolin K, mevastatin, lovastatin and all subsequent statins [simvastatin (Zocor), pravastatin (Pravachol), atorvastatin (Lipitor), fluvastatin (Lescol), rosuvastatin (Crestor)] work by inhibiting HMG Co-A reductase, an enzyme that helps synthesize cholesterol and that is found in the liver.

There have been controlled studies demonstrating that monocolin K reduces cholesterol. A study in China of 4870 patients given red rice yeast over 4.5 years found the incidence of major coronary events (heart attack and death from coronary heart disease) was 5.7% in treated patients and 10.4% in patients given placebo. The active ingredient in red yeast rice appears to be effective in both lowering cholesterol and decreasing the incidence of major coronary events if given in adequate but safe amounts but the overall number of patients tested pales in comparison to those studies done with statins over the last 25 years.

Red yeast rice is usually marketed in 600 mg capsules with a recommendation of taking two tablets twice a day. The effective amount of Monacolin K is probably about 2.5 to 3.2 mg a day. The amount of monacolin K in red yeast rice preparations has been reported to vary by as much as 100-fold (Product review: Red yeast rice supplements. ConsumerLab.com). Red yeast rice is sold as a supplement. The FDA does not regulate supplements. The labels on red yeast rice give no information about content. The amount of Monacolin K in a red yeast rice preparation, the consistency from capsule to capsule or batch to batch is in the unmonitored hands of the manufacturer.

Monacolin K, lovastatin and all statins can cause muscle and liver injury although statins have proved to be very safe when properly dosed and monitored. Very rarely statins and monacolins can cause severe kidney damage. Individuals taking red yeast rice should have periodic blood tests to monitor for liver injury. Muscle pains can result from red yeast rice and statins. The supplement should be stopped immediately for severe muscle pains and/or sudden very dark urine. While there theoretically should be no difference in risk or efficacy from taking RYR and lovastatin, the lack of regulation in the naturaceutical industry means it is buyer beware with RYR as to whether one is getting the right amount of cholesterol lowering medicine (i.e. you might end

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up with not enough and have a higher risk of heart attack or stroke or too much and risk dangerous side effects). Most often, statin dosage can be accurately adjusted by a physician to attain the desired therapeutic effect with a low risk of side effects. This does not hold true for red veast rice.

Mevacor is now available in a generic preparation called lovastatin. It is all but identical to the active ingredient in red yeast rice and is based on a natural substance and production method. Generic preparations of lovastatin and all prescription statins are FDA regulated. The cost for 30 days of RYR is between \$16 and \$37/month. Lovastatin costs about \$22/month. Some discount stores charge as little as \$4 for a 30-day supply.

Aside from the comfort of taking a natural product, it is our opinion that there is little to favor taking red yeast rice over statins that have been tested in tens, if not hundreds of thousands of patients in a controlled and randomized manner to assess efficacy and safety. Statins offer consistency in dosing, low overall risk with proven life-saving efficacy and (in the case of generic lovastatin) equivalent price to red yeast rice.

We encourage our patients to discuss these and any other questions they have regarding options to lower cholesterol.

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