

Red Yeast Rice-Buyer Beware!

I have had an increasing number of patients come and see me who are taking Red Yeast Rice (RYR) as the only means to treat their high cholesterol. Many people make the assumption that this is a “natural medicine” and that it is completely safe to use and actually works. Unfortunately, RYR is not the wonder drug that many folks think that it is and may actually be harmful as I will explain. One must remember that in 2008, there were many products manufactured in China that were found to be tainted with lead and melamine, to name a few of them.

Red Yeast Rice extract is the fermented product of rice on which red yeast has been grown . The active ingredient in red yeast rice is believed to be Monacolin K, an agent reported to be identical to lovastatin (a commonly prescribed statin). Like statins, red yeast has been found to directly reduce lipids. There is little doubt that the proprietary preparation of red yeast rice, known as Cholestin favorably alters lipids. However, due to legal issues, this preparation is no longer commercially available in the US. In 1998, the FDA determined that red yeast rice did not conform to the definition of a dietary supplement under the 1994 Diet supplement and Health Education Act (DSHEA). This act states that marketed dietary supplements cannot contain a compound already approved as a drug (in this case, lovastatin) unless the substance was available commercially before the drug's approval. At present, Cholestin is still available in Canada, Europe and Asia – however, great caution should be exercised because Cholestin has been reformulated and no longer contains the important Red Yeast Rice extract, but rather polymethoxylated flavones extracted from citrus fruits, geraniol and marine fish oils. It is unclear if this or other proprietary preparations of red yeast extract will provide the same lipid effects. The FDA has issued a warning to consumers regarding three brands of red yeast rice. Follow this link for more information. www.fda.gov and type in red yeast rice in the search box.

As a result of a study published in the June 15, 2008 issue of the American Journal of Cardiology, the National Lipid Association felt compelled to write an official statement on this RYR study. This study suggested that a new ingredient of RYR, called Xuezhikang (XZK), may have significant benefits. The published study was a randomized, double-blind, placebo study conducted in Chinese hospitals on 4,870 patients who had a previous heart attack within the past 5 years. The primary endpoint was the occurrence of a major coronary event or death from coronary or cardiac causes. The striking findings of this study are the 45% reduction of the relative risk of major coronary events and the statistically significant reductions in CV and total mortality. The NLA recommended that physicians and patients should beware that the composition of this product is not yet known and any future use will depend on the results of ongoing studies.

XZK is produced by the Beijing WBL Peking University Biotech Co. Ltd and is the purified extract of Chinese RYR with multiple components. This product is not

sold in the USA, lacks FDA approval, and is not identical to other products sold in the USA as “red yeast rice”. This does not mean that this particular brand is not brought into this country illegally. Like the product known as Cholestin, XZK contains lovastatin, plants sterols, and isoflavones. At the present time, it is not known to what extent, if any, lipid- lowering accounts for treatment benefit.

To summarize the current thought on this preparation and all other types of RYR,

1. Physicians should not advise patients to take any RYR supplement as efficacy has not been proven for any indication.
2. If you are taking a medicine for cholesterol management, continue to take your prescripion. Do NOT add any RYR to your current medications as adverse effects may be more likely.
3. RYR should not be substituted for statins. The active ingredients of any of the preparations currently sold in the USA are unknown.