

Active ingredient levels vary among red yeast rice supplements

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Different formulations of red yeast rice, a supplement marketed as a way to improve cholesterol levels, appear widely inconsistent in the amounts of active ingredients they contain, according to a report in the October 25 issue of *Archives of Internal Medicine*. In addition, one in three of 12 products studied had detectable levels of a potentially toxic compound.

"Chinese red yeast rice, also known as Hong Qu, is a medicinal agent and food colorant made by culturing a yeast, Monascus purpureus, on rice," the authors write as background information in the article. The process produces compounds called monacolins, one of which (monacolin K) has been purified and marketed as lovastatin. "Several studies have shown that specific formulations of red yeast rice reduce low-density lipoprotein cholesterol (LDL-C) significantly compared with placebo. This is likely related to the effects of monacolin K and the 13 other monacolins in the supplement, which also works to lower the production of cholesterol in the liver."

In 2008, American consumers spent about \$20 million on this supplement, often in response to recommendations from clinicians. However, to avoid being considered an unapproved drug by the U.S. <u>Food and Drug Administration</u>, manufacturers do not standardize or disclose the levels of monacolin K or other monacolins in their products, the authors note. Ram Y. Gordon, M.D., of Chestnut Hill Hospital, Philadelphia, and Abington Memorial Hospital, Abington, Penn., and colleagues evaluated monacolin levels in 12 commercial red yeast rice



formulations and also tested for citrinin, a toxin from fungus that is potentially harmful to the kidneys.

Across the 12 products, levels of total monacolins ranged from 0.31 milligrams to 11.15 milligrams per capsule and levels of monacolin K or <u>lovastatin</u> ranged from 0.10 milligrams to 10.09 milligrams per capsule. Four of the formulations had elevated levels of citrinin.

"Red yeast rice has been used for centuries for its medicinal properties and is an increasingly popular alternative lipid-lowering therapy that may benefit patients with a history of coronary disease who cannot take statins, subjects who refuse statins or who prefer a 'natural' approach to pharmacotherapy, or patients with a history of statin-associated myalgias," or muscle pains, the authors write.

"However, our study found dramatic variability of monacolin levels in commercial products and the presence of citrinin in one-third of formulations. Further oversight and standardization of the production and labeling of red yeast rice products may address some of the concerns raised in this study. Until these issues are addressed, physicians should be cautious in recommending red yeast rice to their patients for the treatment of hyperlipidemia [high cholesterol] and primary and secondary prevention of cardiovascular disease."

More information: Arch Intern Med. 2010;170[19]:1722-1727.

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