

get the facts

Red Yeast Rice: An Introduction



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Red yeast rice is a traditional Chinese culinary and medicinal product. In the United States, dietary supplements containing red yeast rice have been marketed to help lower blood levels of cholesterol and related lipids. Red yeast rice products may not be safe; some may have the same side effects as certain cholesterol-lowering drugs, and some may contain a potentially harmful contaminant. This fact sheet provides basic information about red yeast rice, summarizes scientific research on effectiveness and safety, discusses the legal status of red yeast rice, and suggests sources for additional information.

Key Facts

- Some red yeast rice products contain substantial amounts of monacolin K, which is chemically identical to the active ingredient in the cholesterol-lowering drug lovastatin. These products may lower blood cholesterol levels and can cause the same types of side effects and drug interactions as lovastatin.
- Other red yeast rice products contain little or no monacolin K. It is not known whether these products have any effect on blood cholesterol levels.
- Consumers have no way of knowing how much monacolin K is present in most red yeast rice products. The labels on these products usually state only the amount of red yeast rice that they contain, not the amount of monacolin K.
- The U.S. Food and Drug Administration (FDA) has determined that red yeast rice products that contain more than trace amounts of monacolin K are unapproved new drugs and cannot be sold legally as dietary supplements.
- Some red yeast rice products contain a contaminant called citrinin, which can cause kidney failure.
- Tell all your health care providers about any complementary health approaches you use. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care.

U.S. DEPARTMENT OF HEALTH
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About Red Yeast Rice

Red yeast rice is made by culturing rice with various strains of the yeast *Monascus purpureus*. Some preparations of red yeast rice are used in food products in Chinese cuisine, including Peking duck. Others have been sold as dietary supplements to lower blood levels of cholesterol and related lipids.

Some red yeast rice products contain substances called monacolins, which are produced by the yeast. Monacolin K is chemically identical to the active ingredient in the cholesterol-lowering drug lovastatin, which is one of the drugs in the category known as statins. These drugs lower blood cholesterol levels by reducing the production of cholesterol by the liver.

The composition of red yeast rice products varies depending on the yeast strains and culture conditions used to manufacture them. The strains and conditions used to produce culinary red yeast rice differ from those used to produce products that are intended to lower cholesterol. Tests performed by the FDA indicate that the red yeast rice sold as a food product contains only traces of monacolin K or none at all.

In both 2008 and 2009, the most recent years for which data are available, sales of red yeast rice dietary supplements were approximately \$20 million per year. According to the 2007 National Health Interview Survey, which included a comprehensive survey of the use of complementary health approaches by Americans, 2.1 percent of respondents (an estimated 1.8 million Americans) had used complementary health approaches for cholesterol in the past year.

Safety

- The same types of side effects that can occur in patients taking lovastatin as a drug can also occur in patients who take red yeast rice products that contain monacolin K. Potential side effects include myopathy (muscle symptoms such as pain and weakness), rhabdomyolysis (a condition in which muscle fibers break down, releasing substances into the bloodstream that can harm the kidneys), and liver toxicity. Each of these three side effects has been reported in people who were taking red yeast rice.
- Red yeast rice supplements should not be used while pregnant or breastfeeding.
- Lovastatin can interact with a variety of drugs to increase the risk of rhabdomyolysis; these drugs include other cholesterol-lowering agents, certain antibiotics, the antidepressant nefazodone, drugs used to treat fungal infections, and drugs used to treat HIV infection. Red yeast rice containing monacolin K could interact with drugs in the same way.
- If the process of culturing red yeast rice is not carefully controlled, a substance called citrinin can form. Citrinin has been shown to cause kidney failure in experimental animals and genetic damage in human cells. In a 2011 analysis of red yeast rice products sold as dietary supplements, 4 of 11 products were found to contain this contaminant.

What the Science Says

Red yeast rice products that contain substantial amounts of monacolin K can lower blood cholesterol levels. Researchers have not reported results of any studies of red yeast rice products that contain little or no monacolin K, so whether these products have any effect on blood cholesterol is unknown.

Results of Clinical Trials

In clinical trials (studies in people) of red yeast rice products that contained substantial amounts of monacolin K, the products lowered blood levels of total cholesterol and low-density lipoprotein (LDL) cholesterol (the so-called bad cholesterol that is linked to increased heart disease risk). It is important to emphasize that all of these clinical trials used products that contained substantial amounts of monacolin K. A 2011 analysis showed that some of the red yeast rice products on the market contain very little monacolin K. These products may have little or no effect on blood cholesterol levels. Therefore, even though the participants in the clinical trials were able to lower their cholesterol levels by taking red yeast rice, you might not be able to achieve the same results.

In one of the clinical trials, the tested product produced a cholesterol-lowering effect greater than would be expected based on its monacolin K content. Further investigations, supported by the National Center for Complementary and Alternative Medicine (NCCAM), suggested that other monacolins or other substances present in the product may have contributed to its cholesterol-lowering effect.

Tolerability of Red Yeast Rice Products

Two studies supported by NCCAM have indicated that some people who had been unable to tolerate statin drugs because of side effects (muscle pain or weakness) were able to tolerate red yeast rice. It is uncertain whether the smaller amount of monacolin K in the red yeast rice products, as compared with the amounts of active ingredients in the drugs, accounted for the greater tolerability or whether other factors were responsible.

Legal Status of Red Yeast Rice

In 1998, the FDA determined that a red yeast rice product that contained a substantial amount of monacolin K was an unapproved new drug, not a dietary supplement. On several occasions since then, the FDA has taken action against companies selling red yeast rice products that contain more than trace amounts of monacolin K, warning them that it is against the law to market these products as dietary supplements.

Despite the FDA actions, some red yeast rice products currently on the market in the United States may contain monacolin K. (Some products tested as recently as 2011 have been found to contain it in substantial amounts.) Other products may contain little or none of this component. Consumers have no way of knowing how much monacolin K is present in most red yeast rice products, and therefore have no way of knowing whether a particular product is safe, effective, or legal. The labels on these products usually state only the amount of red yeast rice that they contain, not the amounts of monacolin K or other monacolins.

If You Are Considering Red Yeast Rice

- Do not use red yeast rice to replace conventional care or to postpone seeing your health care provider about a health problem.
- Do not use red yeast rice dietary supplements if you are pregnant, trying to become pregnant, or nursing a child. If you are considering giving a child a red yeast rice dietary supplement, it is especially important to consult the child's health care provider.
- Do not take red yeast rice in addition to prescription statin drugs.
- Many Web sites, including sales sites, have information about red yeast rice. Be cautious when you evaluate information from the Web; not all of it is trustworthy. For more information, see the NCCAM fact sheet *Evaluating Web-Based Health Resources* at nccam.nih.gov/health/webresources.
- Federal regulations for dietary supplements are very different from—and less strict than—those for drugs. For more information about dietary supplements, see NCCAM's fact sheet *Using Dietary Supplements Wisely* at nccam.nih.gov/health/supplements/wiseuse.htm.
- Tell all your health care providers about any complementary health approaches you use. Give them a full picture of what you do to manage your health. This will help ensure coordinated and safe care. For tips about talking with your health care providers about complementary health approaches, see NCCAM's Time to Talk campaign at nccam.nih.gov/timetotalk.

Key References

- Barnes PM, Bloom B, Nahin RL. Complementary and alternative medicine use among adults and children: United States, 2007. *CDC National Health Statistics Report #12*. 2008.
- Becker DJ, Gordon RY, Halbert SC, et al. Red yeast rice for dyslipidemia in statin-intolerant patients. A randomized trial. *Annals of Internal Medicine*. 2009;150(12):830-839.
- Gordon RY, Becker DJ. The role of red yeast rice for the physician. *Current Atherosclerosis Reports*. 2011;13(1):73-80.
- Gordon RY, Cooperman T, Obermeyer W, et al. Marked variability of monacolin levels in commercial red yeast rice products: buyer beware! *Archives of Internal Medicine*. 2010;170(19):1722-1727.
- Halbert SC, French B, Gordon RY, et al. Tolerability of red yeast rice (2,400 mg twice daily) versus pravastatin (20 mg twice daily) in patients with previous statin intolerance. *American Journal of Cardiology*. 2010;105:198-204.
- Heber D, Lembertas A, Lu QY, et al. An analysis of nine proprietary Chinese red yeast rice dietary supplements: implications of variability in chemical profile and contents. *Journal of Alternative and Complementary Medicine*. 2001;7(2):133-139.
- Klimek M, Wang S, Ogunkanmi A. Safety and efficacy of red yeast rice (*Monascus purpureus*) as an alternative therapy for hyperlipidemia. *P&T: A Peer-Reviewed Journal for Formulary Management*. 2009;34(6):313-327.
- Li Z, Seeram NP, Lee R, et al. Plasma clearance of lovastatin versus Chinese red yeast rice in healthy volunteers. *Journal of Alternative and Complementary Medicine*. 2005;11(6):1031-1038.
- U.S. Food and Drug Administration. *FDA Warns Consumers to Avoid Red Yeast Rice Products Promoted on Internet as Treatments for High Cholesterol: Products Found to Contain Unauthorized Drug*. U.S. Food and Drug Administration Web site. Accessed at www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm108962.htm on March 8, 2012.

For More Information

NCCAM Clearinghouse

The NCCAM Clearinghouse provides information on NCCAM and complementary health approaches, including publications and searches of Federal databases of scientific and medical literature. The Clearinghouse does not provide medical advice, treatment recommendations, or referrals to practitioners.

Toll-free in the U.S.: 1-888-644-6226

TTY (for deaf and hard-of-hearing callers): 1-866-464-3615

Web site: nccam.nih.gov

E-mail: info@nccam.nih.gov

The National Heart, Lung, and Blood Institute (NHLBI)

NHLBI, a component of the National Institutes of Health (NIH), provides global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives.

Web site: www.nhlbi.nih.gov

Office of Dietary Supplements (ODS), NIH

ODS seeks to strengthen knowledge and understanding of dietary supplements by evaluating scientific information, supporting research, sharing research results, and educating the public. Its resources include publications (such as *Dietary Supplements: What You Need to Know*), fact sheets on a variety of specific supplement ingredients (such as vitamin D and black cohosh), and the PubMed Dietary Supplement Subset.

Web site: www.ods.od.nih.gov

E-mail: ods@nih.gov

PubMed®

A service of the National Library of Medicine (NLM), PubMed contains publication information and (in most cases) brief summaries of articles from scientific and medical journals.

Web site: www.ncbi.nlm.nih.gov/sites/entrez

NIH Clinical Research Trials and You

NIH has created a Web site, NIH Clinical Research Trials and You, to help people learn about clinical trials, why they matter, and how to participate. The site includes questions and answers about clinical trials, guidance on how to find clinical trials through ClinicalTrials.gov and other resources, and stories about the personal experiences of clinical trial participants. Clinical trials are necessary to find better ways to prevent, diagnose, and treat diseases.

Web site: www.nih.gov/health/clinicaltrials/

Research Portfolio Online Reporting Tools Expenditures & Results (RePORTER)

RePORTER is a database of information on federally funded scientific and medical research projects being conducted at research institutions.

Web site: projectreporter.nih.gov/reporter.cfm

NIH National Library of Medicine's MedlinePlus

Red Yeast Listing: www.nlm.nih.gov/medlineplus/druginfo/natural/925.html

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