

Is Red Yeast Rice a Safe Alternative to Prescription Cholesterol Medicine?



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If you have high cholesterol, you are probably familiar with a group of cholesterol lowering medications called “statins” commonly known by brand names like Lipitor, Zocor, Crestor etc. Statins are the most effective medicines for lowering bad cholesterol (LDL) which causes atherosclerosis (plaque build-up in blood vessels) leading to heart attack and stroke. But not all persons who can benefit from statins are taking them. Some people have to stop taking statins because of adverse reactions (ARs). As such, they often turn to alternatives like Red Yeast Rice (RYR) – an over the counter (OTC) supplement which has cholesterol-lowering action. In some cases, people opt to take RYR instead of prescription cholesterol medicines because products labeled “natural” appear safer than traditionally-prescribed medicines. But it is important to note that nutritional supplements with RYR contain the same active ingredient as statins, but without the same quality and safety scrutiny by the [Food and Drug Administration](#) [2] [3](FDA) before marketing.

What is RYR? Red Yeast rice, AKA red Koji, originated from Traditional Chinese Medicine and food colorant is a byproduct of fermented rice and food fungus (*Monascus purpureus*). RYR contains an active ingredient called monacalin K, which is chemically identical to the statin called lovastatin. While there have been studies that showed the efficacy of RYR in lowering cholesterol, there is a lack of adequate safety data.

A recent [study](#) [4] published in *Br J Clin Pharmacol*, January 2017 sought to evaluate the safety profile of various nutritional supplements containing RYR. The authors reviewed data from the Italian Surveillance System of Natural Health Products, where anyone can go online to report suspected reactions to nutritional or herbal supplements. Between 2002 and 2015, there were

1261 reports of ARs related to health and dietary supplements, 55 (65%) of which were related to products containing RYR. The most commonly reported brands were Armolipid Plus, 29(55%) and Colestat, 5 (10%). All subjects reported using the supplements for cholesterol lowering purposes, either as a first-time treatment or as an alternative to statin intolerance. A committee of scientists, of various backgrounds, analyzed the reports to determine the likelihood that the reported ARs were indeed caused by RYR. They did this using a scoring system adopted from the World Health Organization (WHO) guidelines for pharmacovigilance.

Reported Reactions to RYR: The most commonly reported reactions were muscle pain, 20 (36%); various gastrointestinal related issues, 12 (22%); liver related problems, 10 (18%); and skin problems, 9 (16%). Of the total reports, 14(27%) were considered serious reactions, 13 of which required hospitalization. Using a standardized scoring system, the likelihood of adverse effect causality was determined to be: Certain in 1, Probable in 31(56%), possible in 18(34%), likely in 3, and indeterminant in 2 of the reports. These results were consistent with a separate WHO database of 75 reports, as well as another registry from the ANSES French Agency, which showed the most reported ARs related to RYR to be muscle and liver related – also similar to reactions commonly reported with statin use.

Reasons for Caution:

1. Dietary supplements are not subject to FDA approval before marketing.
2. The amount of active ingredient (monocalin K) varies among different commercial nutritional supplements. Case in point - in the current study, only 4 out of 23 products contained the European Union (EU) recommended maximum dose of 10mg of monocalin K. A separate [study](#) [5] found that dietary supplements labeled with 600 mg of RYR contained a range of 0.03 mg – 2.18 mg of monocalin K (well below the presumed therapeutic dose), also highlighting the lack of standardization.
3. Nutritional supplements may also contain additional ingredients, which may result in unintended effects. All the products in the Italian study, except one, contained more than RYR. Additional ingredients included green tea, various vitamins, fish oil, resveratrol etc.

Take-Home Message:

- The benefits of statins greatly outweigh their adverse effects.
 - Side effects of statins, such as muscle aches and liver injury, resolve once the medication is stopped.
 - RYR has a similar adverse effect profile to statins but some commercial products may also contain additional ingredients.
 - Unlike nutritional supplements, statins are FDA regulated for quality, safety, and efficacy and are regularly monitored by physicians for known adverse reactions.
 - If you are taking RYR, it is important to inform your doctor.
 - Taking a supplement containing RYR with a statin will likely increase your risk of adverse events and should be avoided.
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