

# FDA adds new safety information to statin drugs

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WASHINGTON (AP) — Federal health officials are adding new safety warnings about risks of memory loss and elevated blood sugar to statins, the most widely prescribed group of cholesterol-lowering medications.

The Food and Drug Administration said Tuesday it is making labeling changes to medicines like Pfizer Inc.'s Lipitor, AstraZeneca's Crestor and Merck & Co. Inc.'s Zocor. The drugs are used by tens of millions of U.S. patients to help prevent heart-related problems associated with cholesterol.

New labeling on all such drugs will warn of memory loss and confusion reported among certain patients taking statins. In general the problems were not serious and went away after patients stopped taking the drugs, according to the FDA.

The updated labels will also mention elevated levels of blood sugar, associated with diabetes, that have been reported in some patients taking statins. A growing number of studies published over the last five years have found a link between statin use and type 2 diabetes. Last June, a report in the Journal of the American Medical Association analyzed five older randomized trials and concluded the increased risk was small but real for people taking higher doses of any statin.

Cardiologists said Tuesday that the lifesaving benefits of statin drugs still drastically outweigh the risks.

"Patients should not see this as a new danger with the drugs, but as a known abnormality that appears in blood testing and should be discussed with their doctor," said Dr. Kevin Marzo, chief of cardiology at Winthrop-University Hospital in New York.

Marzo said the labeling change may lead doctors to monitor patients more closely for diabetes, especially those on high-dose statins, but he does not expect significant changes in how the drugs are prescribed. He urged patients to continue taking their medication as directed.

Statin are mainly prescribed to prevent heart attacks in people with clogged arteries and work by dramatically lowering LDL or "bad cholesterol." They were the third best-selling drug class in the U.S. for 2010 with sales of \$18.8 billion, according to health care data firm IMS Health.

In addition to the label additions, the FDA said it will remove a long-standing warning related to liver injury. The drugs label previously

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"FDA has concluded that serious liver injury with statins is rare and unpredictable in individual patients, and that routine periodic monitoring of liver enzymes does not appear to be effective in detecting or preventing this rare side effect," the agency said in a statement.

In addition to statins, the new labeling changes apply to several combination drugs that mix older statins with newer cholesterol medicines, including Merck's Vytorin and Abbott Laboratories' Simcor.

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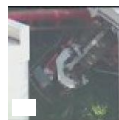
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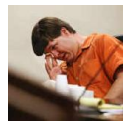
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