

FDA: Use Caution When Prescribing Crestor

Warning Label Change in Europe Prompts FDA Advisory

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June 9, 2004 -- The FDA today advised doctors to be careful about how they prescribe Crestor, a potent cholesterol-fighting drug.

The FDA advisory follows a new warning label released in Europe by Crestor maker Astra-Zeneca Pharmaceuticals. The changes are a response to recent reports of serious toxicity in some patients taking the drug. The new European label stresses that patients over 65, patients with underactive thyroid, and patients with kidney problems may be at particular risk -- especially at the highest dose, 40 mg.

Crestor labels in the U.S. already carry this information, the FDA says.

Crestor is one of the statins, a popular class of cholesterol-lowering drugs. Statins save many lives by reducing the risk of heart disease and stroke. However, all statins have -- to one degree or another -- a dangerous potential side effect. They can injure muscle tissue and can even cause a muscle-destroying disease called rhabdomyolysis. Muscle dissolved during rhabdomyolysis releases substances harmful to the kidney. This can be deadly.

Public Citizen, a U.S. consumer watchdog group, says Crestor is particularly likely to cause rhabdomyolysis and fatal kidney damage. The group opposed the drug's approval and has twice petitioned the FDA to ban Crestor.

The FDA and the drug's manufacturer say Crestor is safe when given to the right patients at the right dose. But Public Citizen maintains that many younger patients taking low doses of the drug have died.

"In an ongoing fashion, we are evaluating these reports of adverse muscle effects with regard to clinical severity and apparent relationship to the drug," the FDA advisory says. "Pending the evaluation of the recent Crestor safety experience, FDA is not proposing to change the U.S. labeling for Crestor, but does want to re-emphasize to physicians the importance of carefully following the recommendations in the current product label."

The FDA stresses several key safety messages regarding Crestor:

Starting doses -- as well as continuing doses -- should be based on each individual patient's cholesterol goals AND on each individual patient's risk of side effects.
Doctors should tell patients that statin drugs can cause muscle injury.
Doctors should tell patients that this muscle injury can be severe. In rare cases, it can lead to life-threatening failure of the kidneys and other organs.

Patients taking Crestor or any other statin, the FDA says, should "promptly" call their doctor if they have:

- Muscle pain or weakness
- Malaise (feeling weak or sick)
- Fever
- Dark urine
- Nausea

Vomiting