

FDA warns of liver damage reports with Sanofi drug

January 14 2011, By MATTHEW PERRONE , AP Health Writer

(AP) -- Federal health officials are warning doctors and patients that a recently-launched heart drug from Sanofi-Aventis SA has been linked to liver damage in a handful of patients.

The [Food and Drug Administration](#) said Friday it has received several reports of [liver damage](#) with Multaq tablets, including two cases in which patients had to have their livers removed. Both patients were women and roughly 70 years old. They had been taking the drug for 4.5 months and 6 months, respectively.

The FDA approved Multaq in July 2009 to treat atrial flutter and [atrial fibrillation](#) which are [irregular heart rhythms](#) that can reduce blood flow and lead to stroke. More than a half-million prescriptions for Multaq have been written since the drug was approved.

In an online notice, the FDA said it would add a new warning about the risk for liver damage to the label of Multaq. The agency said patients should contact their doctor if they experience signs of [liver injury](#), including nausea, vomiting and fever. If doctors suspect a toxicity issue they should discontinue use of the drug and test the patient's liver enzymes.

Liver toxicity is among the most common drug-related side effects across a number of medication classes.

Multaq already carries a black box warning, the most severe type, stating

the drug can cause severe complications, including death, in people with recent severe [heart failure](#) and should not be used in those patients. Common side effects of the twice-a-day tablets include fatigue, loss of strength, diarrhea, nausea and vomiting.

Paris-based Sanofi reported \$84 million in sales for Multaq in the first-half of 2009.

Leerink Swann analyst Seamus Fernandez said the safety warning is unlikely to hurt U.S. sales of drug, which he estimates at \$128 million for 2010 and \$521 million by 2016.

Sanofi said in a statement it has already issued a letter about the liver injuries to doctors and other health care professionals who prescribe Multaq. The letter recommends prescribers consider giving liver enzyme tests during the first six months of treatment.

"Sanofi-Aventis will continue to be in communication with the FDA and this issue will be closely reviewed and monitored," the company stated.

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