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On Drugs and Therapeutics

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IN BRIEF

FDA Warning on Dronedarone *(Multaq)*

The FDA and the manufacturer (Sanofi-Aventis) have warned healthcare professionals that use of dronedarone *(Multaq)*, an analog of amiodarone (*Cordarone*, and others) approved in 2009 for treatment of atrial fibrillation,[1,2] has been associated with "several" cases of severe liver injury and hepatic failure, including two that required liver transplants. Both transplants were in women about 70 years old; one had taken the drug for 4.5 months and the other for 6 months. According to the FDA, 147,000 patients have taken dronedarone.[3] A new warning in the package insert recommends monitoring hepatic enzymes, especially during the first 6 months of treatment.

1. Dronedarone (Multaq) for atrial fibrillation. Med Lett Drugs Ther 2009; 51:78.
2. Treatment of atrial fibrillation. Treat Guidel Med Lett 2010; 8:65.
3. FDA drug safety podcast for healthcare professionals: severe liver injury associated with the use of dronedarone (marketed as Multaq). Available at www.fda.gov. Accessed February 24, 2011.