

# The Medical Letter<sup>®</sup>

## On Drugs and Therapeutics

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Volume 53 (Issue 1359)  
March 7, 2011

[www.medicalletter.org](http://www.medicalletter.org)

### IN BRIEF

#### FDA Warning on Dronedaronone (*Multaq*)

The FDA and the manufacturer (Sanofi-Aventis) have warned healthcare professionals that use of dronedaronone (*Multaq*), an analog of amiodaronone (*Cordaronone*, and others) approved in 2009 for treatment of atrial fibrillation,<sup>1,2</sup> 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 dronedaronone.<sup>3</sup> A new warning in the package insert recommends monitoring hepatic enzymes, especially during the first 6 months of treatment.

1. Dronedaronone (*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 dronedaronone (marketed as *Multaq*). Available at [www.fda.gov](http://www.fda.gov). Accessed February 24, 2011.

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