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On Drugs and Therapeutics

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IN BRIEF

FDA Azithromycin Warning

The FDA has announced that it is requiring changes in the labeling of the macrolide antibiotic azithromycin *(Zithromax, Zmax)* to warn about the risk of QT prolongation and cardiac arrhythmias.[1] The new warnings are based on a retrospective study in *The New England Journal of Medicine* (reviewed previously in *The Medical Letter*[2]), which found that among patients who received 347,795 prescriptions for azithromycin, there were 29 cardiovascular deaths, a significantly higher rate than the 42 that occurred among patients who received 1,348,672 prescriptions for amoxicillin (which does not prolong the QT interval) or the 41 that occurred among 1,391,180 patients who took no antibiotics. The risk with azithromycin was much higher in patients with cardiovascular risk factors.[3]

Other macrolides and fluoroquinolones can also prolong the QT interval. In the retrospective study, the risk of cardiovascular death with levofloxacin was not significantly different from the risk with azithromycin. As with any retrospective study, the possibility that baseline differences between patients taking azithromycin and those taking other or no antimicrobials could have been responsible for the difference in cardiovascular outcomes cannot be entirely ruled out.

1. FDA Drug Safety Communication: Azithromycin (Zithromax or Zmax) and the risk of potentially fatal heart rhythms. Available at www.fda.gov/drugs/drugsafety/ucm341822.htm. Accessed March 14, 2013.
2. In brief: safety of azithromycin. Med Lett Drugs Ther 2012; 54:45.
3. WA Ray et al. Azithromycin and the risk of cardiovascular death. N Engl J Med 2012; 366:1881.

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