Alerts and Recalls

Generic Name (Trade Nameâ€"Company)	**Uses**/Notes
February 28, 2018	
Clarithromycin ***(Multiple trade names—Multiple companies)*** **Potential increased risk of heart problems or death in patients with heart disease**	FDA is advising caution before prescribing the antibiotic clarithromycin to patients with heart disease because of a potential increased risk of heart problems or death that can occur years later. FDA's recommendation is based on a review of the results of a 10-year follow-up study of patients with coronary heart disease from a large clinical trial (the prospective, placebo-controlled CLARICOR trial) that first observed this safety issue. An unexpected increase in deaths occurred among patients with coronary heart disease who received a 2-week course of clarithromycin that became apparent after patients had been followed for 1 year or longer. There is no clear explanation for how clarithromycin would lead to more deaths than placebo. Some observational studies also found an increase in deaths or other serious heart-related problems, while others did not. All the studies had limitations in how they were designed. Of the six observational studies published to date in patients with or without coronary artery disease, two found evidence of long-term risks from clarithromycin, and four did not. As a result, FDA added a new warning about this increased risk of death in patients with heart disease and advised prescribers to consider using other antibiotics in such patients. FDA also added the study results to the clarithromycin drug labels. As part of FDA's usual ongoing safety monitoring of drugs, the agency is continuing to monitor safety reports in patients taking clarithromycin.

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