FDA warns of potentially fatal irregular heart rhythm with azithromycin

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The FDA issued a warning Tuesday that the antibiotic azithromycin, sold by Pfizer as Zithromax and available generically, can cause abnormal changes in the electrical activity of the heart that may lead to a potentially fatal irregular heart rhythm. The notification came after the agency reviewed data, including results of a study published [1] last year in the NEJM, which found that azithromycin was linked with a small increase in cardiovascular deaths and in the risk of death from any cause.

The FDA indicated that caution should be exercised when prescribing azithromycin to patients with prolonged QT interval or known risk factors, including low levels of potassium or magnesium, bradycardia and the use of anti-arrhythmia treatment. The regulator added that other macrolide and non-macrolide antibiotics can potentially cause QT prolongation and that these risks should be considered when selecting an antibiotic.

Last year, the agency issued [2] a response to the NEJM study to inform doctors of the risk of QT prolongation associated with certain antibiotics and to advise patients to continue taking their medicine unless directed to stop by their physician. The FDA also revised the warning label of Zithromax last year to reflect the risk of QT prolongation, which it described as low.