U.S. Department of Health & Human Services

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health
U.S. Food & Drug Administration

Safety

Zithromax (azithromycin): FDA Statement on risk of cardiovascular death

Audience: Primary Care, Pharmacy

ISSUE: FDA notified healthcare professionals that it is aware of the study published in the *New England Journal of Medicine* May 17, 2012 [1] [2] reporting a small increase in cardiovascular deaths, and in the risk of death from any cause, in persons treated with a 5-day course of azithromycin (Zithromax) compared to persons treated with amoxicillin, ciprofloxacin, or no drug. FDA is reviewing the results from this study and will communicate any new information on azithromycin and this study or the potential risk of QT interval prolongation after the agency has completed its review.

BACKGROUND: Azithromycin belongs to a class of antibacterial drugs called macrolides, which have been associated with cardiovascular effects; specifically, prolongation of the QT interval. In 2011, FDA reviewed macrolide drug labeling information related to QT interval prolongation and TdP. The WARNINGS AND PRECAUTIONS section of the Zmax drug label (azithromycin extended release for oral suspension) was revised in March 2012 to include new information regarding risk for QT interval prolongation, which appears to be low. The drug labels for clarithromycin and erythromycin also contain information about QT interval prolongation in the WARNINGS section. FDA is in the process of updating risk information in the drug labels for additional macrolide antibacterial drugs.

RECOMMENDATION: Patients taking azithromycin should not stop taking their medicine without talking to their healthcare professional. Healthcare professionals should be aware of the potential for QT interval prolongation and heart arrhythmias when prescribing or administering macrolides.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm [3]
- Download form [4] or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[05/17/2012 - Statement [5] - CDER]

[03/15/2012 - Azithromycin Prescribing Information [6] - Pfizer]

[03/15/2012 - MedWatch Safety Labeling [7] - FDA]

[05/03/2012 - Clarithromycin Prescribing Information [8] - Abbott]

Links on this page:

1. http://www.nejm.org/doi/full/10.1056/NEJMoa1003833
2. http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm
3. http://www.fda.gov/MedWatch/report.htm
4. /Safety/MedWatch/HowToReport/DownloadForms/default.htm
5. /Drugs/DrugSafety/ucm304372.htm
6. http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/050797s016lbl.pdf
7. /Safety/MedWatch/SafetyInformation/ucm262866.htm
8. http://www.accessdata.fda.gov/drugsatfda_docs/label/2012/050662s044s050,50698s026s030,050775s015s019lbl.pdf