MedWatch The FDA Safety Information and Adverse Event Reporting Program

Azithromycin (Zithromax or Zmax): Drug Safety Communication – Risk of Potentially Fatal Heart Rhythms

[Posted 03/12/2013]

FDA警示，azithromycin (Zithromax or Zmax)可能引起心臟電位改變，造成致命心律不整的風險。有此特別風險的病人包含：已知有QT波延長、低血鉀、低血鎂、心律過慢、或使用某些治療心律不整的藥物。FDA發布藥品安全訊息，乃根據研究人員回顧文獻以及藥品製造商所作文獻的結果。

FDA於2012年5月17日發表一則聲明：有一項實驗研究心血管疾病死亡的風險，研究對象為使用抗生素的患者(包含azithromycin、amoxicillin、ciprofloxacin、levofloxacin)，以及沒有使用抗生素的患者。這項研究指出：使用5天療程azithromycin，相較於使用amoxicillin、ciprofloxacin、或沒使用抗生素，其死亡的風險較高(無論是心血管疾病死亡，或者其他任何原因造成的死亡)。使用levofloxacin的組別，心血管死亡風險與azithromycin組別類似。

建議

面對可能有心血管事件風險的患者，醫療人員在選擇藥品時，應考量azithromicin可能造torsades de pointesc和致命心律不整。另外，選擇抗生素藥物時，除了考量azithromicin可能有QT波延長的風險；其餘macrolide類的藥品、非macrolides類的藥品如fluoroquinolones，也有QT波延長的潛在風險或其他嚴重的副作用。

[Posted 03/12/2013]

AUDIENCE: Family Practice, Patient, Pharmacy, Health Professional

ISSUE: FDA is warning the public that azithromycin (Zithromax or Zmax) can cause abnormal changes in the electrical activity of the heart that may lead to a potentially fatal irregular heart rhythm. Patients at particular risk for developing this condition include those with known risk factors such as existing QT interval prolongation, low blood levels of potassium or magnesium, a slower than normal heart rate, or use of certain drugs used to treat abnormal heart rhythms, or arrhythmias. FDA has issued a Drug Safety Communication today as a result of our review of a study by medical researchers as well as another study by a manufacturer of the drug that assessed the potential for azithromycin to cause abnormal changes in the electrical activity of the heart.

FDA previously released a Statement on May 17, 2012, about a study that compared the risks of cardiovascular death in patients treated with the antibacterial drugs azithromycin, amoxicillin, ciprofloxacin (Cipro), and levofloxacin (Levaquin), or no antibacterial drug. The study reported an 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. The risks of cardiovascular death associated with levofloxacin treatment were similar to those associated with azithromycin treatment.

BACKGROUND: Azithromycin is marketed under the brand names Zithromax and Zmax. FDA-approved indications for azithromycin include: acute bacterial exacerbations of chronic obstructive pulmonary disease, acute bacterial sinusitis, community-acquired pneumonia, pharyngitis/tonsillitis, uncomplicated skin and skin structure infections, urethritis and cervicitis, genital ulcer disease.

RECOMMENDATION: Health care professionals should consider the risk of torsades de pointes and fatal heart rhythms with azithromycin when considering treatment options for patients who are already at

risk for cardiovascular events. FDA notes that the potential risk of QT prolongation with azithromycin should be placed in appropriate context when choosing an antibacterial drug: Alternative drugs in the macrolide class, or non-macrolides such as the fluoroquinolones, also have the potential for QT prolongation or other significant side effects that should be considered when choosing an antibacterial drug.