THE REGIONAL EMERGENCY MEDICAL SERVICES COUNCIL OF NEW YORK CITY, INC.

NYC REMAC

Advisory No.	2011-06		
Title:	**FDA Caution for Zofran (Ondansetron)**		
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The Regional Emergency Medical Advisory Committee (REMAC) of New York City has been made aware of a recent U.S. Food and Drug Administration (FDA) drug safety communication regarding Zofran (ondansetron). Although, **REMAC NYC is not removing ondansetron from ALS Protocol 531: Severe Nausea/Vomiting**, it was recommended that ALS Agency Medical Directors, On Line Medical Control Physicians and Paramedics be made aware of the FDA statements.

Zofran (ondansetron and ondansetron hydrochloride) is used to prevent nausea and vomiting. It is in a class of medications called 5-HT3 receptor antagonists and works by blocking the action of serotonin, a natural substance that may cause nausea and vomiting.

The FDA stated the anti-nausea drug Zofran (ondansetron, ondansetron hydrochloride and generics) may increase the risk of developing abnormal changes in the electrical activity of the heart, specifically, prolongation of the QT interval which can lead to an abnormal and potentially fatal heart rhythm (*torsades de pointes*).

Patients at particular risk for developing *torsades de pointes* include those with underlying heart conditions, such as congenital long QT syndrome, those who are predisposed to low levels of potassium or magnesium in the blood, and those taking other medications that lead to QT prolongation. Additionally, the FDA recommends ECG monitoring in patients with electrolyte abnormalities (e.g., hypokalemia or hypomagnesemia), congestive heart failure, bradyarrhythmias, or in patients taking other medications that can lead to QT prolongation when Zofran (ondansetron) is administered. (Note that ECG monitoring is recommended, but not required).

ALS agency medical directors are required to report to REMAC any patient who develops *torsades de pointes* or other ventricular tachycardia, as well as any patient who experiences cardiac arrest, following the administration of Zofran (ondansetron).

Additional information is available at: http://www.fda.gov/Drugs/DrugSafety/ucm271913.htm

Current and Updated Protocols can be accessed at the Regional EMS Council website: www.nycremsco.org.

Owners/operators of Ambulance and ALS First Response Services providing prehospital medical treatment within the five boroughs of the City of New York are responsible to provide copies of the NYC REMAC Prehospital Treatment Protocols to their personnel, and to ensure that Service Medical Directors and EMS personnel are informed of all changes/updates to the NYC REMAC Prehospital Treatment Protocols.

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Chair, Regional Emergency Medical Advisory Committee of New York City

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SEVERE NAUSEA / VOMITING

For adult and pediatric patients with persistent vomiting or severe nausea

1. Begin Basic Life Support Abdominal Pain procedures.
2. Begin an IV/Saline Lock infusion of Normal Saline (0.9% NS).
3. Monitor vital signs every 5 minutes.
4. Consider and treat, as per the appropriate protocol, underlying causes of the patient's nausea/vomiting (i.e. Poisoning, Myocardial Ischemia, etc).
5. Administer Ondansetron 0.1mg/kg (not to exceed 4mg), IV or Saline Lock bolus, slowly over 1-2 minutes. For continued vomiting, a repeat dose of 0.1mg/kg (not to exceed 4mg) may be administered. (Maximum total dose is 8mg.)