

Drug Alert: Ondansetron (Zofran)

On Wednesday September 15, 2011, the United States' Food and Drug Administration (FDA) issued a safety alert about the drug ondansetron (Zofran). The purpose of this alert is to notify patients and medical professionals of an ongoing safety review and labeling changes for the drug ondansetron. The safety review is occurring because ondansetron **may** "increase the risk of developing prolongation of the QT interval of the electrocardiogram, which can lead to an abnormal and potentially fatal heart rhythm." We would like to emphasize that ondansetron has not been shown to increase this risk, but it is a possibility that is currently being investigated. **Ondansetron/Zofran is believed to be safe for the general population at present.**

The FDA has recommended that patients avoid taking ondansetron only if they suffer from congenital long QT syndrome. They are also changing the drug's labeling to include a recommendation for EKG monitoring in patients with electrolyte abnormalities, congestive heart failure, bradyarrhythmias, or in patients taking other medications that can lead to QT prolongation (such as amitriptyline). If you are concerned about you or your child taking ondansetron, we suggest that you contact the medical professional who manages your or your child's CVS. *Please do not make any changes to any medication without your physician's approval.* Please contact your physician as you may need a baseline EKG in view of this recent announcement by the FDA. This alert has not been extended to other medications in the same class such as granisetron (Kytril) which may be a suitable alternative.

The FDA is also asking patients and professionals to report any adverse events or side effects related to ondansetron use to the FDA's Med Watch Safety Information and Adverse Event Reporting Program. To report an adverse event online, complete and submit a report at www.fda.gov/MedWatch/report.htm.

The complete drug alert can be located online at <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm272041.htm>. We recommend that you bring a copy of this FDA alert to your next appointment with the physician who manages your CVS if you are taking ondansetron. They may have not seen the alert as it was addressed to an Oncology and Anesthesiology professionals.

CVSA Primary Medical Advisors

Robert M. Issenman, M.D.
Professor of Pediatrics
GI McMaster University – Hamilton, Ontario

Thangam Venkatesan, M.D.
Associate Professor, Medicine-GI Medical College Wisconsin
Director, Program Adults with CVS - Milwaukee

Alerted by:
Bhanu Sunku, M.D.
Assistant Professor Pediatrics, GI, Director Clinical Serv & Educ.
Floating Hosp for Children – Tufts Med Center - Boston