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## Zofran® (ondansetron) (Abnormal Heart Rhythms – Labeling Change)

### NOTICE

On September 15, 2011 the FDA notified healthcare professionals and patients of the possible development of heart rhythm abnormalities observed with the use of ondansetron (Zofran).

### BACKGROUND

Ondansetron is a serotonin agonist anti-emetic FDA indicated for the prevention of nausea and vomiting associated with chemotherapy, radiation therapy, and surgery. Due to recent concerns regarding drug-related cardiovascular events, some which may be fatal, ondansetron's drug label will be modified to indicate the potential for development of cardiac abnormalities (QT prolongation and Torsade de Pointes) which may be possible with the use of the medication. Patients with underlying heart conditions and low blood levels of potassium and magnesium are at an increased risk for ondansetron-related cardiac anomalies. In addition to the labeling revision indicated above, ondansetron's drug label will include a recommendation for ECG monitoring in patients with certain conditions including electrolyte abnormalities, congestive heart failure, bradyarrhythmias, or in those taking other medications with may affect the QT interval.

### RECOMMENDED ACTIONS

At this time, the FDA is requiring labeling modifications to both brand and generic formulations of ondansetron to include information about the potential for cardiac abnormalities in patient's utilizing this agent. The FDA is currently requiring GlaxoSmithKline to perform a clinical study examining the effect that ondansetron has on the QT interval in an effort to provide clinicians with more detailed dosing/usage information. The FDA has communicated these issues, as well as changes to the product labeling, to all healthcare professionals. Given the relatively low utilization of ondansetron in workers' compensation, it is expected that this side effect will be encountered very infrequently in the injured worker population.

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