MedWatch The FDA Safety Information and Adverse Event Reporting Program

Zofran (ondansetron): Drug Safety Communication - Risk of Abnormal Heart Rhythms

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FDA 通知醫療人員與患者：目前正針對 ondansetron 做安全性審查與仿單修改。Ondansetron 會增加心電圖的 QT 波延長，可能導致致命的心律不整，例如 Torsade de Pointes。有 Torsade de Pointes 之風險性的患者，包含有潛在心臟疾病(如先天性 QT 波延長)，或是血鉀、血鎂太低，或者是服用會導致 QT 波延長的藥物。

Ondansetron 的仿單正在修改內容，如下：避免將本藥品用於有先天 QT 波延長的患者，因為有 Torsade de Pointes 的風險。建議有以下情況的使用者，須監控心電圖變化，包含電解質不正常(低血鉀或低血鎂)、充血性心衰竭、心跳過慢、或使用會導致 QT 波延長的藥物

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AUDIENCE: Oncology, Anesthesiology

ISSUE: FDA notified healthcare professionals and patients of an ongoing safety review and labeling changes for the anti-nausea drug Zofran (ondansetron, ondansetron hydrochloride and generics). 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, including Torsade de Pointes. Patients at particular risk for developing Torsade de Pointes include those with underlying heart conditions, such as congenital long QT syndrome, those who are predisposed to low levels of potassium and magnesium in the blood, and those taking other medications that lead to QT prolongation.

RECOMMENDATION: The labels are being revised to include a warning to avoid use in patients with congenital long QT syndrome because these patients are at particular risk for Torsade. Recommendations for 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, are being included in the labels.