

## Product Withdrawals

Generic Name (Trade Name—Company)

Uses/Notes

December 5, 2012

**Ondansetron**

**(Zofran—GlaxoSmithKline, various generics)**

**High-dose removed from the market**

The 32-mg single I.V. dose of ondansetron has been pulled from the market, [FDA announced yesterday](#), because of concerns related to cardiac adverse events. In June, the agency warned that the 32-mg dose should be avoided because of the risk of QT interval prolongation, which can lead to torsade de pointes. Preliminary results of a study ordered by the FDA found a maximum mean difference in QTcF of 20 ms after the 32 mg intravenous dose, compared with a QTcF difference of 6 ms for the 8 mg intravenous dose.

FDA noted that removal of the 32-mg dose should not contribute to a potential ondansetron shortage, as this dose only made up a small percentage of the current market. The agency also noted that it will continue to recommend an I.V. regimen of 0.15 mg/kg administered every 4 hours for three doses to prevent chemotherapy-induced nausea and vomiting. Oral ondansetron was also discussed as an effective alternative for the management of chemotherapy-induced nausea and vomiting.

### **Source URL:**

<http://aphanet.org/product-withdrawals/high-dose-removed-market>

A<sup>PhA</sup> DrugInfoLine is an official publication of, and is owned and copyrighted by the American Pharmacists Association, the national professional society of pharmacists. Materials in A<sup>PhA</sup> DrugInfoLine do not necessarily represent the policy, recommendations, or endorsement of A<sup>PhA</sup>. The publisher, authors, editors, reviewers, and contributors have taken care to ensure that information contained in A<sup>PhA</sup> DrugInfoLine is accurate and current; however, they shall have no liability to any person or entity with regard to claims, losses, or damages caused or alleged to be caused, directly or indirectly, by use of any information contained in the publication. All decisions about drug therapy must be based on the independent judgment of the clinician. Copyright © 2000–2011, American Pharmacists Association. All rights reserved.