

(<http://www.aphanet.org>)

[Home](#) > High-dose removed from the market

Generic Name:

Ondansetron

Trade Name:

Zofran

Company:

GlaxoSmithKline, various generics

Notes:

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.

Medication Monitor Categories:

[Product Withdrawals](#)

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