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FDA: Zofran 32-mg dose pulled from market

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The 32-mg, single intravenous dose of Zofran (ondansetron), an anti-nausea drug, is being removed from the market due to its potential to cause serious, even fatal, cardiac damage, according to a Drug Safety Communication issued Dec. 4 by the U.S. Food and Drug Administration.

(HealthDay)—The 32-mg, single intravenous dose of Zofran (ondansetron), an anti-nausea drug, is being removed from the market due to its potential to cause serious, even fatal, cardiac damage, according to a Drug Safety Communication (DSC) issued Dec. 4 by the U.S. Food and Drug Administration.

The agency issued a prior DSC in late June 2012 recommending that this particular dose of Zofran be avoided due to the risk of prolonged QT interval, which can lead to torsades de pointes, a potentially fatal heart rhythm.

The FDA does continue to recommend Zofran administered intravenously at 0.15 mg/kg every four hours for patients experiencing chemotherapy-related nausea and vomiting, with no single dose exceeding 16 mg. The agency is working with manufacturers of all

branded and generic 32-mg intravenous ondansetron injectable products to recall them from the market and anticipates the product will be removed through early 2013.

According to a press release issued by the agency, the FDA "does not anticipate that removal of the 32-mg intravenous dose of ondansetron currently sold as pre-mixed injections will contribute to a drug shortage of intravenous ondansetron, as the 32-mg dose makes up a very small percentage of the current market."

More information: More Information

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