MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

Ondansetron (Zofran) 32 mg, Single Intravenous (IV) Dose: Updated Safety Communication – Product Removal due to Potential For Serious Cardiac Risks

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FDA通知醫療人員，單次靜脈注射32 mg ondansetron會增加潛在嚴重心血管疾病風險，因而此劑量規格將不再上市。

FDA建議預防化療引起噁心嘔吐之療程為：靜脈注射0.15 mg/kg，每4個小時給予一次劑量，總共給予三個劑量。口服ondansetron亦對預防化療引起的噁心和嘔吐有效。但FDA目前尚未提出可替代之單次靜脈注射療程。

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AUDIENCE: Oncology, Surgery, Health Professional

ISSUE: FDA is notifying health care professionals that the 32 mg, single intravenous (IV) dose of the anti-nausea drug Zofran (ondansetron hydrochloride) will no longer be marketed because of the potential for serious cardiac risks.

BACKGROUND: The 32 mg, single IV dose of Zofran had been used to prevent chemotherapy-induced nausea and vomiting. A previous Drug Safety Communication (DSC), issued on June 29, 2012, communicated that the 32 mg, single IV dose should be avoided due to the risk of a specific type of irregular heart rhythm called QT interval prolongation, which can lead to Torsades de Pointes, an abnormal, potentially fatal heart rhythm. These drugs are sold pre-mixed in solutions of either dextrose or sodium chloride in plastic containers.

FDA anticipates these products will be removed from the market through early 2013. 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 IV ondansetron, as the 32 mg dose makes up a very small percentage of the current market

RECOMMENDATION: FDA continues to recommend the intravenous regimen of 0.15 mg/kg administered every 4 hours for three doses to prevent chemotherapy-induced nausea and vomiting. Oral dosing of Ondansetron remains effective for the prevention of chemotherapy-induced nausea and vomiting. At this time, there is not enough information available for FDA to recommend an alternative single IV dose regimen.