Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Fresenius Kabi Issues Voluntary Nationwide Recall of Midazolam Injection, USP, 2 mg/2 mL Due to Reports of Blister Packages Containing Syringes of Ondansetron Injection, USP, 4 mg/2 mL

For Immediate Release

November 3, 2017

Contact

Consumers

1-866-716-2459

Media

Matt Kuhn
matt.kuhn@fresenius-kabi.com (mailto:matt.kuhn@fresenius-kabi.com)
(847) 550-5751

Announcement

Fresenius Kabi USA is voluntarily recalling Lot 6400048 of Midazolam Injection, USP, 2 mg/2 mL packaged in a 2 mL prefilled single-use glass syringe to the hospital/user level. The product mislabeled as Midazolam Injection, USP, 2 mg/2 mL contains syringes containing and labeled as Ondansetron Injection, USP, 4 mg/2 mL.

A missed dose of midazolam may lead to ineffective sedation and/or anxiety related to patient recall of a surgical or diagnostic procedure. If a selection error occurs, a patient who may have received a pre-operative dose of ondansetron may inadvertently receive an additional dose of ondansetron. Dose-dependent serious cardiac arrhythmias may be observed with higher dosages of ondansetron in those patients with certain pre-existing cardiac conditions. Patients may

also be at risk for serotonin syndrome. Serotonin syndrome is associated with increased serotonergic activity in the central nervous system. Most reports of serotonin syndrome have been associated with concomitant use of certain drugs, some commonly used during surgery, such as fentanyl. Some of the reported cases of serotonin syndrome were fatal.

Fresenius Kabi USA has not received any reports of adverse events related to this recall.

Midazolam is indicated for sedation, anxiety, and for induction of general anesthesia. It is packaged in a 2 mL prefilled single-use glass syringe, packaged in a blister with 24 blisters per carton, NDC 76045-001-20, product code 766120.

The affected Midazolam Injection, lot 6400048, expires July 2018. Ondansetron is indicated for the prevention of nausea and vomiting associated with cancer chemotherapy treatments and for prevention of postoperative nausea and/or vomiting. Product was distributed nationwide in the United States between May 12, 2017 and October 18, 2017 to wholesale distributors.

Fresenius Kabi is notifying its distributors and customers by letter and is arranging for return of the recalled product. If health care facilities have the affected lot, they are to immediately discontinue distributing, dispensing or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers that have been shipped, or may have been shipped the product involved in this recall.

Consumers with questions regarding this recall can contact Fresenius Kabi Quality Assurance at 1-866-716-2459. Consumers should contact their physician or health care provider if they have experienced any problems that may be related to receiving this drug product.

Adverse reactions or quality problems experienced with the use of this product may be reported to Fresenius Kabi Medical Affairs or Vigilance departments at 1-800-551-7176, Monday through Friday, during the hours of 8:00 a.m. to 5:00 p.m. Central Standard Time, or send an e-mail to either **productcomplaint.USA@fresenius-kabi.com (mailto:productcomplaint.USA@fresenius-kabi.com)** or **adverse.events.USA@fresenius-kabi.com (mailto:adverse.events.USA@fresenius-kabi.com)**

Adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/medwatch/report.htm)**
- Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)** or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

###

More in Recalls, Market Withdrawals, & Safety Alerts (/Safety/Recalls/default.htm)

Archive for Recalls, Market Withdrawals & Safety Alerts (/Safety/Recalls/ArchiveRecalls/default.htm)

Enforcement Reports (/Safety/Recalls/EnforcementReports/default.htm)

Industry Guidance (/Safety/Recalls/IndustryGuidance/default.htm)

Major Product Recalls (/Safety/Recalls/MajorProductRecalls/default.htm)