

## Fresenius Kabi – Recall of midazolam injection

- On October 30, 2017, [Fresenius Kabi announced](#) a voluntary, user-level recall of one lot of [midazolam](#) 2 mg/2 mL injection due to a report of two blister packages labeled as midazolam injection 2 mg/2 mL, lot 6400048 containing syringes of [ondansetron](#) injection 4 mg/2 mL, lot 6400069.

Description	NDC	Lot # (Expiration Date)
Midazolam injection, 2 mg/2 mL, 1 mL fill in a 2 mL single use glass syringe packaged in a blister package	76045-001-20	6400048 (7/2018)

- Midazolam injection is indicated for the following:
  - Intramuscularly or intravenously for preoperative sedation/anxiolysis/amnesia
  - Intravenously as an agent for sedation/anxiolysis/amnesia prior to or during diagnostic, therapeutic or endoscopic procedures (eg, bronchoscopy, gastroscopy, cystoscopy) either alone or in combination with other central nervous system depressants
  - Intravenously for induction of general anesthesia, before administration of other anesthetic agents. With the use of narcotics premedication, induction of anesthesia can be attained within a relatively narrow dose range and in a short period of time. Intravenous (IV) midazolam can also be used as a component of IV supplementation of nitrous oxide and oxygen (balanced anesthesia)
  - Continuous IV infusion for sedation of intubated and mechanically ventilated patients as a component of anesthesia or during treatment in a critical care setting
- Ondansetron injection is indicated for the prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including high-dose cisplatin and for the prevention of postoperative nausea and/or vomiting.
- Per Fresenius Kabi, a blister package labeled as midazolam injection, but containing ondansetron injection may lead to an initial product selection error; however, the syringe in the blister package is visible and clearly labelled as containing ondansetron injection. To date, there have been no medication errors or adverse events reported for the recalled lot of midazolam injection.
- Anyone with an existing inventory of the recalled midazolam injection should stop use and distribution, and contact Fresenius Kabi Quality Assurance Department at **1-866-716-2459** for return information. Contact Fresenius Kabi Vigilance/Medical Affairs at **1-800-551-7176** for any clinical questions regarding the recall.
- Patients should contact their healthcare provider if they have experienced any problems that may be related to using the recalled product.