

Dexmedetomidine Hydrochloride Injection Recall Alert

Date of Notice: 11/19/2020

Brief Description of Recall Alert

Fresenius Kabi USA is voluntarily recalling a single lot of dexmedetomidine HCl in 0.9% sodium chloride injection, 200 mcg/50 mL (4 mcg /mL), 50 mL fill in a 50 mL vial. Fresenius Kabi initiated this recall due to a trace amount of lidocaine present in the lot. This recall is being performed to the user level.

Dexmedetomidine hydrochloride in 0.9% sodium chloride injection is approved for intravenous use and indicated for sedation of non-intubated patients prior to and/or during surgical and other procedures.

Affected Products

Drug Name & Strength	NDC	Lot	Expiration Date
dexmedetomidine HCl in 0.9% sodium chloride injection, 200 mcg / 50 mL (4 mcg / mL), 50 mL fill in a 50 mL vial	63323-671-50	6123925	03/2022

Prescriber Information

To date, no adverse drug experience reports have been received for the recalled lot. Administration of dexmedetomidine HCl containing trace amounts of lidocaine to a patient with lidocaine allergy could result in a potentially life-threatening allergic reaction.

Adverse reactions or issues experienced with the use of this drug may 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](#)
- Regular Mail or Fax: [Download the form](#) 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

Member Information

Fresenius Kabi is notifying its distributors and customers by letter and asking them to check their stock immediately and to quarantine and discontinue the use and distribution of any affected product.

Distributors should notify their customers and direct them to quarantine and discontinue distributing or dispensing any affected lots, and to return the product to Fresenius Kabi. The recall letter and response form is available at <https://www.freseniuskabi.com/us/pharmaceutical-product-updates>.

This document is designed to be an informational resource to facilitate discussion and should be used neither as a basis for clinical decision-making or treatment nor as a substitute for reading original literature. RxAdvance makes every effort to ensure that the information provided is up-to-date, accurate, and complete, but no guarantee is made to that effect. If this information is provided to clients or vendors, it is subject to any contractual confidentiality provisions. Third-party disclosures are in violation of confidentiality provisions.

Customers with questions regarding this recall may contact Fresenius Kabi at 1-866-716-2459 Monday through Friday, during the hours of 8:00 a.m. to 5:00 p.m. Central Time. Consumers should contact their physician or health care provider if they have experienced any problems that may be related to taking or using this drug product.

RxAdvance Response

RxAdvance recommends that you speak to your doctor before you stop taking the drug.

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