

COMPANY ANNOUNCEMENT

Fresenius Kabi Issues Voluntary Nationwide Recall of a Single Lot of Dexmedetomidine Hydrochloride Injection Due to Cross-Contamination of Lidocaine

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.

[Read Announcement](#)[View Product Photos](#)

Summary

Company Announcement Date:

November 19, 2020

FDA Publish Date:

November 19, 2020

Product Type:

Drugs

Reason for Announcement:

Cross Contamination with Lidocaine

Company Name:

Fresenius Kabi USA

Brand Name:

Fresenius Kabi USA

Product Description:

Dexmedetomidine HCL in 0.9% Sodium Chloride Injection

Company Announcement

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.



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.

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.

Listed below is a table of the recalled lot distributed nationwide to wholesalers, distributors, hospitals and pharmacies between April 9, 2020 and April 13, 2020. An image of the label is also included below.

<u>Product Name/Product size</u>	<u>NDC Number</u>	<u>Product Code</u>	<u>Batch Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
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	671050	6123925	03/2022	04/09/2020	04/13/2020

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 are available at <https://www.freseniuskabi.com/us/pharmaceutical-product-updates> (<https://www.freseniuskabi.com/us/pharmaceutical-product-updates>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>). (<https://www.freseniuskabi.com/us/pharmaceutical-product-updates>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)

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.

Adverse reactions or quality problems experienced with the use of this product 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 (</safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda>)

- Regular Mail or Fax: Download form (</safety/medical-product-safety-information/medwatch-forms-fda-safety-reporting>) 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
- Or, contact Fresenius Kabi at 1-800-551-7176, Monday through Friday, during the hours of 8:00 a.m. to 5:00 p.m. Central Time or via email at: 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>)

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

Company Contact Information

Consumers:

Fresenius Kabi

☎ 1-866-716-2459

Product Photos



🔍 More Recalls, Market Withdrawals, & Safety Alerts (</safety/recalls-market-withdrawals-safety-alerts>)