Clifton Health Department
Food Recall Notification

Food/Drug/Pet Recall: Fresenius Kabi USA

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.

Product Name/Product size NDC Number Product Code Batch Number Expiration Date First Ship Date Last Ship 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 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

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
. Regular Mail or Fax: Download 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
. 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.comor adverse.events.USA@fresenius-kabi.com

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