RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Dexmedetomidine Hydrochloride Injection Recall Alert

Date of Notice: 07/22/2020

Brief Description of Recall Alert

Fresenius Kabi USA is voluntarily recalling two lots 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 the possibility of a trace amount of lidocaine present in these two lots and their investigation indicates that this issue is limited to these two product lots. This recall is being performed to the user level.

To date, no adverse drug experience reports have been received for either of the lots being recalled by Fresenius Kabi. Administration of dexmedetomidine HCl containing trace amounts of lidocaine to a patient with lidocaine allergy, however, could result in anaphylaxis, a potentially life-threatening condition.

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	6121853	05/2021
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	612220	06/2021

Prescriber Information

Adverse reactions or quality problems experienced with the use of this drug should 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

Member Information

Fresenius Kabi is notifying its distributors and customers by letter and asking customers and distributors 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.fresenius- kabi.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.

RxAdvance Response

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