

URGENT DRUG RECALL

July 22, 2020

<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	6121853	05/2021	06/03/2019	12/04/2019
			6122207	06/2021	03/12/2020	04/08/2020

Dear Customer/Health Professional:

This letter is to notify you that Fresenius Kabi USA, LLC ("Fresenius Kabi") is voluntarily recalling the above-mentioned batches of Dexmedetomidine HCl in 0.9% Sodium Chloride Injection, 200 mcg / 50 mL (4 mcg / mL), 50 mL fill in a 50 mL vial.

This recall is being performed to the user level. Fresenius Kabi has decided to take this action due to the possibility of a trace amount of lidocaine present in the above-listed batches. The investigation reveals that this issue is limited to the product batches indicated above.

Administration of Dexmedetomidine HCl containing trace amounts of lidocaine to a patient with lidocaine allergy, could result in anaphylaxis which is a life threatening condition.

To date, no adverse drug experience reports have been received for either of the lots being recalled by Fresenius Kabi.

You are required to **DESTROY** all product from the above-mentioned batches that you have in your possession. To implement this recall, please do the following:

1. Examine your stock **immediately** to determine if you have any product vials from the affected batches. Quarantine any affected stock. If you are a distributor, immediately notify your customers that have been shipped or may have been shipped this product of this recall and direct them to quarantine and discontinue distributing or dispensing the affected batches. Please have them prepare to **DESTROY** the product. Your customers may retrieve the recall letter and response form at <https://www.fresenius-kabi.com/us/pharmaceutical-product-updates>.
2. If you have the affected batches available, **immediately quarantine and discontinue distributing, dispensing, or using** the batches, and **DESTROY** all vials using your current vendor / hauler of non-hazardous regulated medical waste. A credit memo will **NOT** be issued covering the quantity until a letter of destruction is received from you.
3. **PLEASE COMPLETE THE ENCLOSED "URGENT PRODUCT RECALL RESPONSE FORM" AND SEND IT BACK TO US IMMEDIATELY VIA EMAIL TO FK-NARECALLS@FRESENIUS-KABI.COM OR FAX AT 1-708-649-8630.**

CONTACT NUMBERS: Use the following contact phone numbers. Hours of operation: Monday through Friday 8:00 am to 5:00 pm CST

<u>Number</u>	<u>Department</u>	<u>Reason to Call</u>
(866) 716-2459	Quality Assurance Department	Information on how to return product
(800) 551-7176	Vigilance or Medical Affairs	For clinical/technical information/Adverse Events (ADE) reporting

This recall is being made with the knowledge of the United States Food and Drug Administration (FDA).

We apologize for any inconvenience this voluntary recall may cause you.

Sincerely,



Melanie Power-Burns
Senior Vice President Quality Assurance

URGENT PRODUCT RECALL RESPONSE FORM
URGENT: DRUG RECALL - Sterile Injectable
July 22, 2020
Please complete and fax to: 1-708-649-8630
To: Fresenius Kabi USA, LLC

Attn:

Quality Assurance Department

<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	6121853	05/2021	06/03/2019	12/04/2019
			6122207	06/2021	03/12/2020	04/08/2020

1. Examine your inventory **immediately** to determine if you have any product from the above-mentioned batches.
2. If so, **immediately** discontinue distribution or dispensing of the affected batches and **DESTROY** all units using your current vendor / hauler of non-hazardous regulated medical waste. A credit memo will NOT be issued covering the quantity until a letter of destruction is received from you.

3. **PLEASE COMPLETE THIS FORM AND SEND IT BACK TO US IMMEDIATELY VIA EMAIL AT FK-NARECALLS@FRESENIUS-KABI.COM OR FAX AT 1-708-649-8630.**

 We currently do not have units of the batch numbers on hand.

We are **DESTROYING** _____ Vials We are **DESTROYING** _____ Trays/Cartons

 I have identified and contacted direct account customers indicated below that have been shipped or may have been shipped this product. They have prepared to **DESTROY** the product.

FROM: Hospital (other): _____

Street Address: _____

City, State, Zip code: _____

Signature: _____

From:

FACILITY:

ADDRESS:

CITY, STATE, ZIP:

Signature _____

Date: _____