

## URGENT DRUG RECALL

November 17, 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>
<b>Dexmedetomidine HCl in 0.9% Sodium Chloride Injection, 200 mcg / 50 mL (4 mcg / mL), 50 mL fill in a 50 mL vial</b>	<b>63323-671-50</b>	<b>671050</b>	<b>6123925</b>	<b>03/2022</b>	<b>04/09/2020</b>	<b>04/13/2020</b>

Dear Customer/Health Professional:

This letter is to notify you that Fresenius Kabi USA, LLC (“Fresenius Kabi”) is voluntarily recalling the above-mentioned batch 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 low level carryover of lidocaine present in the above-listed batch.

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 the above batch being recalled by Fresenius Kabi.

You are required to return all product from the above-mentioned batch 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 batch. Quarantine any affected stock. If you are a distributor, immediately notify your customers that have been shipped or may have been shipped this product and direct them to quarantine and discontinue distributing or dispensing the affected batch. Please have them prepare to return the product to Fresenius Kabi (see enclosed information). 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 batch available, **immediately quarantine and discontinue distributing, or dispensing** any vials from the batch, and return all vials to Fresenius Kabi, USA, LLC located at 600 Supreme Drive, Bensenville, IL 60106, via FedEx Ground, using the enclosed return goods label and packing slip. A FedEx Ground label can be obtained by checking the box and noting your mailing address on the enclosed Urgent Product Recall Response Form. It will be mailed to you upon receiving your request. A credit memo will be issued covering the quantity of your return to Fresenius Kabi USA, LLC.
3. **PLEASE COMPLETE THE ENCLOSED “URGENT PRODUCT RECALL RESPONSE FORM” AND SEND IT BACK 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 Drug Event (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**
**November 17, 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	6123925	03/2022	04/09/2020	04/13/2020

1. Examine your inventory **immediately** to determine if you have any product from the above-mentioned batch.
2. If so, **immediately** discontinue distribution or dispensing of the affected batch and return all units to Fresenius Kabi USA, LLC located at 600 Supreme Drive, Bensenville, IL 60106 via FedEx Ground using the enclosed return goods label and packing slip. A credit memo will be issued covering the quantity of your return to Fresenius Kabi USA, LLC.  
**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.**
3.  We currently do not have units of the batch number on hand.
- We are returning \_\_\_\_\_ vials **OR** \_\_\_\_\_ trays/cartons  
# of Labels needed \_\_\_\_\_
- I have identified contacted direct account customers that have been shipped or may have been shipped this product. Please send FedEx Ground Shipping Labels to the address below.

FROM: Hospital (other): \_\_\_\_\_

Street Address: \_\_\_\_\_

City, State, Zip code: \_\_\_\_\_

Signature: \_\_\_\_\_

**From:**

FACILITY:

ADDRESS:

CITY, STATE, ZIP:

**Signature** \_\_\_\_\_

**Date** \_\_\_\_\_



**ATTN: URGENT DRUG RECALL**

**PACKING SLIP FOR VOLUNTARY RECALL**

<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>
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**Vials (1 each) OR**

**Trays/Cartons Returning (Circle One)**

\_\_\_\_\_

Hospital (other) \_\_\_\_\_

Street Address \_\_\_\_\_

City, State, Zip code \_\_\_\_\_

Signature \_\_\_\_\_

***PLEASE ENCLOSE THIS FORM WITH YOUR RETURN***