URGENT DRUG RECALL

July 22, 2020

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**	**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 return 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 and direct them to quarantine and discontinue distributing or dispensing the affected batches. 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 batches available, **immediately** quarantine and discontinue distributing, or dispensing any vials from the batches, 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

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

FRESENIUS KABI

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

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**	**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 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.
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 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** _____

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Main: 847-550-2300
Toll Free: 888-391-6300
www.fresenius-kabi.com/us

FRESENIUS KABI

ATTN: URGENT DRUG RECALL

PACKING SLIP FOR VOLUNTARY RECALL

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

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

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Main: 847-550-2300
Toll Free: 888-391-6300
www.fresenius-kabi.com/us