FRESENIUS KABI

URGENT DRUG RECALL

September 17, 2021

Product Name/Product size	NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Morphine Sulfate Injection, USP, 2 mg / mL, 1 mL fill in a 2 mL amber vial	**63323-452-01**	**475201**	**6023731**	**03/2023**	**05/18/2021**	**06/07/2021**
			6023732	**03/2023**	**06/07/2021**	**06/24/2021**
			6024172	**06/2023**	**07/19/2021**	**08/04/2021**
			6024260	**06/2023**	**08/17/2021**	**08/25/2021**

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 Morphine Sulfate Injection, USP, 2 mg / mL, 1 mL fill in a 2 mL amber vial.

This recall is being performed to the user level. Fresenius Kabi has decided to take this precautionary action after a complaint investigation into empty and low fill vials revealed small cracks in the heel of these vials. The investigation revealed that this issue is limited to the product and batches indicated above.

A cracked vial is a potential container integrity issue, and administration of product from a non-integral vial could result in the introduction of environmental and biologic contaminants, possibly leading to an inflammatory response or infection. No associated adverse event reports have been received for these batch numbers.

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 of this recall 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, return all vials to Inmar Rx Solutions, Inc. A DEA Form 222 is required to return this product. It can be obtained along with a shipping label by completing the enclosed Urgent Product Recall Response Form, noting your intent to return product, address, and phone number, and DEA number. The form and label will be sent to you upon receiving your completed response form. A credit memo will be issued covering the quantity of your return.

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 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

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

URGENT PRODUCT RECALL RESPONSE FORM

URGENT: DRUG RECALL – Sterile Injectable

September 17, 2021 **Please complete and fax to: 1-708-649-8630**

To: Fresenius Kabi USA, LLC **Attn:** Quality Assurance Department

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			6024260	**06/2023**	**08/17/2021**	**08/25/2021**

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 Inmar Rx Solutions, Inc.. A DEA Form 222 is required to return this product and will be sent to you upon receipt of a completed response form. A credit memo will be issued covering the quantity of your return.
3. **PLEASE COMPLETE THE INFORMATION BELOW AND SEND BACK TO US IMMEDIATELY VIA EMAIL AT FK-NARECALLS@FRESENIUS-KABI.COM OR FAX TO 1-708-649-8630.**

☐ We currently **do not** have units of the above-mentioned batch numbers on hand.

☐ We are returning: _____ vials **OR** _____ trays/cartons

# of Shipping Labels needed _____

Please send DEA Form 222 and shipping labels to the address below:

From: Hospital (other):_____ DEA #_____

Street Address:_____

City, State, Zip code: _____

Contact Name (Please Print)_____ Telephone#_____

Contact Email_____ Fax#_____

Signature:_____ Date_____

☐ I have identified and contacted direct account customers that have been shipped or may have been shipped this product.

From:
Facility:
Street Address:
City, State, Zip Code:

Signature:_____ Date_____

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

Main: 847-550-2300
Toll Free: 888-391-6300
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FRESENIUS KABI

ATTN: URGENT DRUG RECALL

PACKING SLIP FOR VOLUNTARY RECALL

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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

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Lake Zurich, IL 60047

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