

URGENT DRUG RECALL

September 17, 2021

<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>
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 **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 Drug 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

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

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

<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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			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 **DESTROY** all units using your current vendor / hauler of non-hazardous regulated medical waste. A credit memo will **NOT** be issued covering the quantity of your return until a letter of destruction is received.
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 **DESTROYING**: _____ vials **OR** _____ trays/cartons

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. They have prepared to **DESTROY** the product.

From:

Facility:

Street Address:

City, State, Zip Code:

Signature: _____ Date _____