FRESENIUS KABI

URGENT DRUG RECALL

August 04, 2026

Product Name/Product size	Unit of Use NDC Number	Unit of Sale NDC Number	Product Code	Lot Number	Expiration Date	First Ship Date	Last Ship Date
Morphine Sulfate Injection USP, Simplist® 2 mg / 1 mL, 1 mL fill in a single dose 1 mL Simplist® prefilled syringe	**76045-004-01**	**76045-004-11**	**764411**	**6402820**	**12/2028**	**01/29/2026**	**06/09/2026**

Dear Customer/Health Professional:

This letter is to notify you that Fresenius Kabi USA, LLC ("Fresenius Kabi") is voluntarily recalling the above-mentioned lot of Morphine Sulfate Injection USP, Simplist® 2 mg / 1 mL, 1 mL fill in a single dose 1 mL Simplist® prefilled syringe.

This recall is being conducted to the user level. Fresenius Kabi is taking this precautionary action following a report that a small number of correctly labeled Dilaudid® (HYDROmorphone HCl) Injection, USP Simplist® 0.5 mg/0.5 mL syringes (lot 6402813) were inadvertently mixed into a subsequent packaging lot and distributed in cartons labeled as Morphine Sulfate Injection USP, Simplist® 2 mg/1 mL (lot 6402820). The investigation revealed that this issue is limited to the product and lot indicated above. Refer to Attachment A for product labeling.

Use of a MicroVault labeled as Morphine Sulfate Injection 2 mg/mL containing a prefilled syringe of Dilaudid (hydromorphone HCl) 0.5 mg/0.5 mL has a reasonable probability of causing serious adverse health consequences, including life-threatening respiratory depression and death. Patients at greatest risk include individuals who do not use opioids on a regular basis, those with underlying respiratory disease, pediatric patients, and those who are also taking central nervous system (CNS) depressants. To date, no adverse reports have been received for this lot number.

You are required to return all product from the above-mentioned lot 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 syringes from the affected lot. 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 lot. Please have them prepare to return the product to Inmar Rx Solutions (see enclosed information). Your notification to your customers may be enhanced by including a copy of this recall notification letter. 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 lot available, **immediately** quarantine and discontinue distributing, or dispensing any syringes from the lot, return all syringes 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
855-860-7311	Inmar Rx Solutions	Return kit and DEA Form 222 information

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,

Anthony Giessert, PhD
Senior Vice President Quality Assurance
Fresenius Kabi USA, LLC

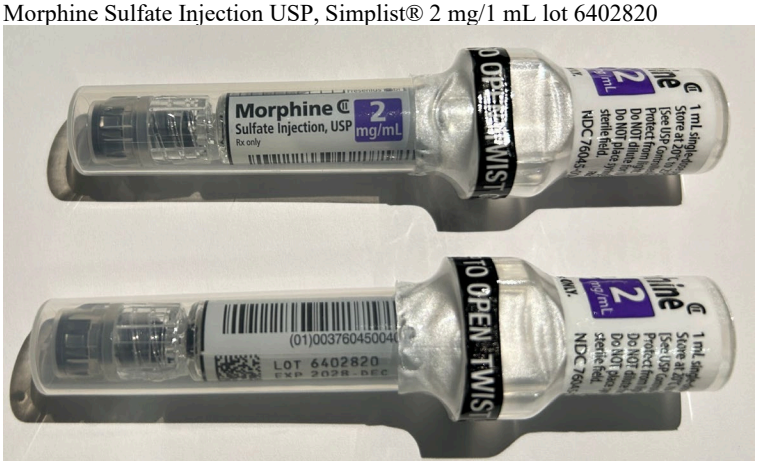
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

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

URGENT DRUG RECALL

Attachment A
Product Labeling

Correct Product Configuration:
Morphine Sulfate Injection USP, Simplist® 2 mg/1 mL lot 6402820



Incorrect Product Configuration:
Morphine Sulfate Injection USP, Simplist® 2 mg/1 mL seal with Dilaudid (HYDROmorphone HCl) Injection, USP Simplist® 0.5 mg/0.5 mL syringes (lot 6402813)

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FRESENIUS KABI

URGENT: DRUG RECALL

URGENT DRUG RECALL RESPONSE FORM

August 04, 2026

Please complete and fax or email to: 1-708-649-8630 or FK-NARECALLS@FRESENIUS-KABI.COM

Product Name/Product Size	Unit of Use NDC Number	Unit of Sale NDC Number	Product Code	Lot Number	Expiration Date	First Ship Date	Last Ship Date
Morphine Sulfate Injection USP, Simplist® 2 mg / 1 mL, 1 mL fill in a single dose 1 mL Simplist® prefilled syringe	76045-004-01	76045-004-11	764411	6402820	12/2028	01/29/2026	06/09/2026

1. Examine your inventory **immediately** to determine if you have any product from the above-mentioned lot.

2. If so, **immediately** discontinue distribution or dispensing of the affected lot and return all units to Inmar Rx Solutions. 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 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 lot number on hand.

☐ We are returning _____ Syringes **OR** _____ Trays/Cartons

# of box labels needed _____

4. I have identified and contacted direct account customers that have been shipped or may have been shipped this product. They have prepared to return the product.

YES ☐ I do not have direct account customers ☐

Customer Name: **DEA #:**

DEA # is required, if it is not provided, the processing of your form will be delayed.

Address:

City: **State:** **Zip:**

Contact Name (Please Print):

Phone: **Email:**

Contact Signature: **Date:**

Wholesaler Information if not directly purchased from Fresenius Kabi USA, LLC:

Wholesaler Name: **DEA #:**

City: **State:** **Zip:**

If you have any questions regarding this form or product return please contact Inmar at 855-860-7311(office hours 9am to 5pm EST Monday through Friday excluding holidays).

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