FRESENIUS KABI

URGENT DRUG RECALL

November 06, 2025

Product Name/Product Size	Unit of Use NDC Number	Unit of Sale NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Famotidine Injection, USP, 20 mg per 2 mL (10 mg per mL), 2 mL fill in a 2 mL vial	**63323-739-11**	**63323-739-12**	**730912**	**6133156**	**08/2026**	**01/02/2025**	**02/11/2025**
				6133194	**08/2026**	**02/04/2025**	**04/11/2025**
				6133388	**10/2026**	**04/15/2025**	**05/23/2025**

Dear Customer/Healthcare Professional:

This letter is to notify you that Fresenius Kabi USA, LLC ("Fresenius Kabi") is voluntarily recalling the above-mentioned batches of Famotidine Injection, USP, 20 mg per 2 mL (10 mg per mL), 2 mL fill in a 2 mL vial.

This recall is being performed to the user level. Fresenius Kabi has decided to take this action due to out-of-specification (OOS) endotoxin results of certain reserve samples for batch 6133194 that were tested as part of an investigation for non-serious adverse event reports. Based upon current investigation, batches 6133156 and 6133388 are also included in this recall as a precautionary measure. Please refer to Attachment A for label examples.

The Health Hazard Evaluation concluded moderate risk to patients. Non-serious adverse event reports potentially associated with the OOS have been received for batch 6133194. No adverse event reports have been received for batches 6133156 and 6133388 to date. Elevated endotoxin levels can precipitate severe systemic reactions such as sepsis and septic shock. Severe responses may include inflammatory and life-threatening immune responses and death.

You are required to **DESTROY** all product from the above-mentioned batch numbers 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 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 DRUG 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

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 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,

Anthony Giessert, Ph.D.
Senior Vice President, Quality Assurance
Fresenius Kabi USA, LLC

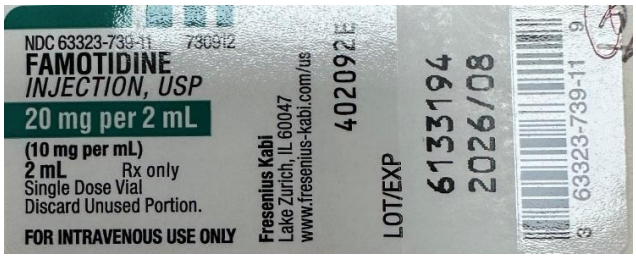
Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

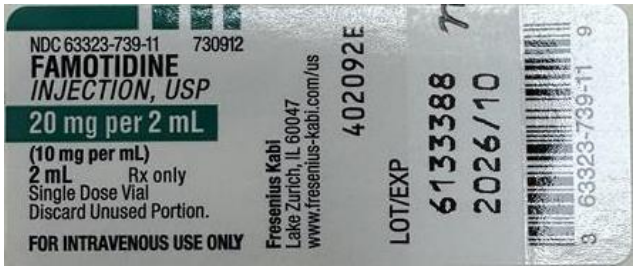
Main: 847-550-2300
Toll Free: 888-391-6300
www.fresenius-kabi.com/us

FRESENIUS KABI

URGENT DRUG RECALL

Attachment A
Labeling Examples





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URGENT: DRUG RECALL – Sterile Injectable

URGENT DRUG RECALL RESPONSE FORM

November 06, 2025 **Please complete and fax to: 1-708-649-8630**

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

Product Name/Product Size	Unit of Use NDC Number	Unit of Sale NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Famotidine Injection, USP, 20 mg per 2 mL (10 mg per mL), 2 mL fill in a 2 mL vial	**63323-739-11**	**63323-739-12**	**730912**	**6133156**	**08/2026**	**01/02/2025**	**02/11/2025**
				6133194	**08/2026**	**02/04/2025**	**04/11/2025**
				6133388	**10/2026**	**04/15/2025**	**05/23/2025**

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 until a letter of destruction is received from you.

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 number on hand.

☐ We are **DESTROYING** _____ Vials ☐ We are **DESTROYING** _____ Trays/Cartons

☐ I have identified and contacted direct account customers indicated below that have been shipped or may have been shipped this product. They have prepared to **DESTROY** the product.

FROM: Hospital (other):_____

Street Address:_____

City, State, Zip code: _____

Signature:_____

From:

FACILITY:
ADDRESS:
CITY, STATE, ZIP:
Signature: _____ **Date:** _____

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