FRESENIUS KABI

URGENT DRUG RECALL

SECOND NOTICE – EXPANSION OF ONE (1) ADDITIONAL BATCH

January 05, 2021

Product Name/Product size	NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Ketorolac Tromethamine Injection, USP, 60 mg / 2 mL (30 mg / mL), 2 mL fill in a 2 mL amber vial	**63323-162-02**	**160202**	**6121125**	**02/2021**	**4/10/2019**	**05/23/2019**
Ketorolac Tromethamine Injection, USP, 30 mg / mL, 1 mL fill in a 2 mL amber vial	**63323-162-01**	**160201**	**6121083**	**02/2021**	**03/28/2019**	**09/03/2019**

Dear Customer/Health Professional:

NOTE: This letter contains one (1) additional batch as noted above in yellow. The previously issued letter, dated 12/17/2020, did not include product code 160201, batch number 6121083. All other information contained within this letter remains unchanged.

This letter is to notify you that Fresenius Kabi USA, LLC ("Fresenius Kabi") is voluntarily recalling the above-mentioned batches of Ketorolac Tromethamine Injection, USP, 60 mg / 2 mL (30 mg / mL), 2 mL fill in a 2 mL amber vial and Ketorolac Tromethamine Injection, USP, 30 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 action due to particulate matter found in reserve sample vials.

Administration of products containing particulate matter could obstruct blood vessels and result in local irritation of blood vessels, swelling at the site of injection, a mass of tissue that could become inflamed and infected, blood clots traveling to the lung, scarring of the lung tissues, and allergic reactions that could lead to life-threatening consequences. No 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 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 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

URGENT PRODUCT RECALL RESPONSE FORM

URGENT: DRUG RECALL – Sterile Injectable
SECOND NOTICE – EXPANSION OF ONE (1) ADDITIONAL BATCH

January 05, 2021 **Please complete and fax to: 1-708-649-8630**

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

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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

SECOND NOTICE – EXPANSION OF ONE (1) ADDITIONAL BATCH

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

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