

URGENT DRUG RECALL

April 20, 2020

<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>
Ketorolac Tromethamine Injection, USP, 30 mg / mL, 1 mL fill in a 2 mL amber vial	63323-162-01	160201	6118737	04/2020	05/30/2018	06/27/2018
			6118902	04/2020	08/01/2018	08/15/2018
			6119052	05/2020	06/25/2018	07/25/2018
			6119752	08/2020	09/28/2018	12/06/2018
			6122349	07/2021	09/16/2019	11/04/2019
			6122538	09/2021	11/01/2019	12/16/2019
Ketorolac Tromethamine Injection, USP, 60 mg / 2 mL (30 mg / mL), 2 mL fill in a 2 mL amber vial	63323-162-02	160202	6119229	06/2020	08/09/2018	10/30/2018
			6119273	06/2020	09/26/2018	03/30/2019
			6119843	09/2020	11/11/2019	01/07/2020
			6121115	02/2021	03/30/2019	04/22/2019
			6121451	03/2021	04/29/2019	08/05/2019
			6121452	03/2021	07/12/2019	10/22/2019
			6121496	03/2021	06/21/2019	12/10/2019

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 Ketorolac Tromethamine Injection, USP, 30 mg / mL, 1 mL fill in a 2 mL amber vial and Ketorolac Tromethamine Injection, USP, 60 mg / 2 mL (30 mg / mL), 2 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 eight (8) reserve sample vials. The investigation reveals that this issue is limited to the product batches indicated above.

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.

To date, there have been no reports of serious adverse events received by Fresenius Kabi. There have been no reports of particulate matter observed by customers for any of the batches.

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

<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 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
Sr Vice President Quality Assurance

URGENT PRODUCT RECALL RESPONSE FORM

URGENT: DRUG RECALL - Sterile Injectable

April 20, 2020

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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			6121452	03/2021	07/12/2019	10/22/2019
			6121496	03/2021	06/21/2019	12/10/2019

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 _____



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

Fresenius Kabi USA, LLC
2045 N. Cornell
Melrose Park, IL 60160

Main: 708-343-6100
Toll Free: 888-391-6300
www.fresenius-kabi.com/us