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 **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

| 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,

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

| 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** |

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 numbers 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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