FRESENIUS KABI

URGENT DRUG RECALL - UPDATED INFORMATION

January 19, 2018

Product Name/Product size	NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
Vecuronium Bromide for Injection, 10 mg per vial in a 10 mL vial	**63323-781-10**	**780110**	**ZG603**	**11/2018**	**04/28/2017**	**05/11/2017**

Dear Customer/Healthcare Professional:

NOTE: This letter contains an updated batch expiry as noted above. The batch expiry was previously listed as "10/2018" and has been corrected to "11/2018." 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 batch of Vecuronium Bromide for Injection, 10 mg per vial in a 10 mL vial.

This recall is being performed to the user level. Fresenius Kabi is taking this action due to a recall notification from our third party manufacturer for an out-of-specification (OOS) result for USP related compound F at the 12 month stability test station for batch ZG603. The investigation reveals this issue is limited only to the specific batch of the product indicated above.

Related compound F, or 3-Desacetyl Vecuronium, is an active metabolite of Vecuronium Bromide. The potential risk to patients due to the OOS is considered to be low. No adverse events have been reported for this batch of Vecuronium Bromide for Injection.

You are required to **DESTROY** all product from the above-mentioned batch 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 batch. 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 discontinue distributing or dispensing the affected batch. Please have them prepare to **DESTROY** the product. Your customers may retrieve the recall letter and response form at http://www.fresenius-kabi.us/products/pharmaceutical-products/product-updates.html.

2. If you have the affected batch available, **immediately** discontinue distributing, dispensing, or using the batch, 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 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
Vice President Quality Assurance

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

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

FRESENIUS KABI

URGENT PRODUCT RECALL RESPONSE FORM

URGENT: DRUG RECALL – Sterile Injectable

January 19, 2018 **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 batch.
2. If so, **immediately** discontinue distribution or dispensing of the affected batch 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(s) on hand.

☐ We are **DESTROYING** _____ vials **OR** _____ 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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