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 return 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 return the product to Fresenius Kabi (see enclosed information). 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 or dispensing any vials from the batch, 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 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
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

| 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** |

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 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 number(s)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** _____



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