

## URGENT DRUG RECALL

April 05, 2016

<u>Product Name/Product Size</u>	<u>NDC Number</u>	<u>Product Code</u>	<u>Lot Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
Cisatracurium Besylate Injection, 2 mg/mL, 10mL fill in a 10 mL vial	63323-417-10	417010	6010157	01/2017	08/11/2015	02/23/2016

Dear Customer/Health Professional:

This letter is to notify you that Fresenius Kabi USA, LLC ("Fresenius Kabi"), is voluntarily recalling the above-mentioned product lot as a precautionary measure. This recall is being performed to the user level. Fresenius Kabi USA, LLC has decided to take this action due to an incorrect statement of "Preservative free" on the individual carton label. The vial label and outer carton label contain the correct statement of "0.9% benzyl alcohol added as a preservative."

Incorrect information on the individual carton label may lead to a product selection error. However, the label on the vial is correctly labeled as containing 0.9% benzyl alcohol added as a preservative. There have been no medication errors or adverse events reported for this lot of Cisatracurium Besylate Injection, 2 mg/mL, 10mL fill in a 10 mL vial.

You are required to return all product from the above-mentioned lot 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 from the affected lot. 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 lot. 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 lot available, **immediately discontinue distributing or dispensing** the lot, 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 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.
3. **PLEASE COMPLETE THE ENCLOSED "URGENT PRODUCT RECALL RESPONSE FORM" AND SEND IT BACK TO US IMMEDIATELY VIA EMAIL AT 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 Events (ADEs) reporting

This recall is being made with the knowledge of the US Food and Drug Administration (FDA). We apologize for any inconvenience this recall may have caused you.

Sincerely,



Melanie Power-Burns  
Vice President Quality Assurance

**URGENT PRODUCT RECALL RESPONSE FORM**
**URGENT: DRUG RECALL - Sterile Injectable**
**April 05, 2016**
**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>Lot Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
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1. Examine your inventory **immediately** to determine if you have any product from the above-mentioned lots.
2. If so, **immediately** discontinue distribution or dispensing of the affected lots 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 FAX IT BACK TO US IMMEDIATELY AT 1-708-649-8630.**
  - We currently do not have units of the lot 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** \_\_\_\_\_