FRESENIUS KABI

URGENT DRUG RECALL

April 05, 2016

Product Name/Product Size	NDC Number	Product Code	Lot Number	Expiration Date	First Ship Date	Last Ship Date
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 **DESTROY** all product from the above-mentioned lots 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 lots. 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 lots. 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 lots available, **immediately** discontinue distributing or dispensing the lots, 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 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

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 (ADEs) reporting

This recall is being made with the knowledge of the US Food and Drug Administration (FDA).

We apologize for any inconvenience this voluntary recall may have caused 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

April 05, 2016 **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	Lot Number	Expiration Date	First Ship Date	Last Ship Date
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**

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 **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 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 **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** _____

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

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