

URGENT DRUG RECALL

December 10, 2020

<u>Product Name/Product size</u>	<u>NDC Number</u>	<u>Product Code</u>	<u>Batch Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
Sensorcaine®-MPF with Epinephrine (Bupivacaine HCl and Epinephrine Injection, USP), 0.5%, 150 mg / 30 mL (5 mg / mL), 30 mL fill in a 30 mL vial	63323-462-37	460237	6123760	02/2022	07/27/2020	08/25/2020

Dear Customer/Health Professional:

This letter is to notify you that Fresenius Kabi USA, LLC (“Fresenius Kabi”) is voluntarily recalling the above-mentioned batch of Sensorcaine®-MPF with Epinephrine (Bupivacaine HCl and Epinephrine Injection, USP), 0.5%, 150 mg / 30 mL (5 mg / mL), 30 mL fill in a 30 mL vial.

This recall is being performed to the user level. Fresenius Kabi USA, LLC has decided to take this action due to out-of-specification (OOS) results for epinephrine assay at the 8-month stability test station. The investigation reveals that this issue is limited to the product batch indicated above.

The Health Hazard Evaluation concluded that the OOS epinephrine value observed is unlikely to be clinically significant. No adverse event reports have been received for this batch number.

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. 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 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 <https://www.fresenius-kabi.com/us/pharmaceutical-product-updates>.
2. If you have the affected batch available, **immediately quarantine and 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

<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 Drug 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
Senior Vice President Quality Assurance

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047

Main: 847-550-2300
Toll Free: 888-391-6300
www.fresenius-kabi.com/us

URGENT PRODUCT RECALL RESPONSE FORM
URGENT: DRUG RECALL - Sterile Injectable
December 10, 2020
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>Batch 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 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 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 _____



ATTN: URGENT DRUG RECALL

PACKING SLIP FOR VOLUNTARY RECALL

<u>Product Name/Product size</u>	<u>NDC Number</u>	<u>Product Code</u>	<u>Batch Number</u>	<u>Expiration Date</u>	<u>First Ship Date</u>	<u>Last Ship Date</u>
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Vials (1 each) OR

Trays/Cartons Returning (Circle One)

Hospital (other) _____

Street Address _____

City, State, Zip code _____

Signature _____

PLEASE ENCLOSE THIS FORM WITH YOUR RETURN