

November 22, 2022

<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® with Epinephrine (Bupivacaine HCl and Epinephrine Injection, USP), 0.25%, 125 mg / 50 mL (2.5 mg / mL), 50 mL fill in a 50 mL vial	63323-461-57	460157	6128061	03/2024	06/20/2022	06/21/2022
			6128663	05/2024	09/21/2022	09/27/2022
			6128664	05/2024	09/23/2022	10/03/2022
Sensorcaine® with Epinephrine (Bupivacaine HCl and Epinephrine Injection, USP), 0.5%, 250 mg / 50 mL (5 mg / mL), 50 mL fill in a 50 mL vial	63323-463-57	460357	6128399	04/2024	07/25/2022	08/18/2022
			6128400	04/2024	07/27/2022	08/18/2022
			6128401	04/2024	08/15/2022	10/31/2022
Sensorcaine®-MPF with Epinephrine (Bupivacaine HCl and Epinephrine Injection, USP), 0.25%, 25 mg / 10 mL (2.5 mg / mL), 10 mL fill in a 10 mL vial	63323-468-17	460817	6128800	12/2023	09/14/2022	09/16/2022

Dear Customer/Healthcare Professional:

This letter is to notify you that Fresenius Kabi USA, LLC (“Fresenius Kabi”) is voluntarily recalling the above-mentioned batches of Sensorcaine® with Epinephrine (Bupivacaine HCl and Epinephrine Injection, USP), 0.25%, 125 mg / 50 mL (2.5 mg / mL), 50 mL fill in a 50 mL vial, Sensorcaine® with Epinephrine (Bupivacaine HCl and Epinephrine Injection, USP), 0.5%, 250 mg / 50 mL (5 mg / mL), 50 mL fill in a 50 mL vial, and Sensorcaine®-MPF with Epinephrine (Bupivacaine HCl and Epinephrine Injection, USP), 0.25%, 25 mg / 10 mL (2.5 mg / mL), 10 mL fill in a 10 mL vial.

This recall is being performed to the user level. Fresenius Kabi has decided to take this action due to testing results below the defined limit for epinephrine impacting batches 6128061, 6128664, 6128399, and 6128800. Batch 6128663 is included in this recall as it was manufactured in the same filling campaign as 6128664 and has exhibited lower than expected results. Batches 6128400 and 6128401 are included in this recall as they were manufactured in the same filling campaign as batch 6128399 and have exhibited lower than expected results.

The Health Hazard Evaluation concluded that the epinephrine levels observed are unlikely to be clinically significant. No adverse event reports have been received for these batch numbers.

You are required to return all product from the above-mentioned batches 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 batches. 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 batches. 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 batches available, **immediately quarantine and discontinue distributing, or dispensing** any vials from the batches, and return all vials to Fresenius Kabi, USA, LLC located at 11900 122nd Street, Pleasant Prairie, WI 53158, 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 DRUG 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

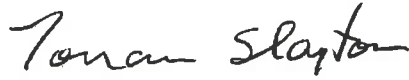
<u>Number</u>	<u>Department</u>	<u>Reason to Call</u>
(866) 716-2459	Quality Assurance Department	Information on how to return product
(800) 551-7176	Vigilance or Medical Affairs	For clinical/technical information/Adverse Drug Event (ADE) reporting

URGENT DRUG RECALL

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,



Torrance Slayton
Vice President Quality Assurance

URGENT DRUG RECALL RESPONSE FORM

November 22, 2022

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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			6128663	05/2024	09/21/2022	09/27/2022
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- Examine your inventory **immediately** to determine if you have any product from the above-mentioned batches.
- If so, **immediately** discontinue distribution or dispensing of the affected batches and return all units to Fresenius Kabi USA, LLC located at 11900 122nd Street, Pleasant Prairie, WI 53158 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.

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

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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

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