

The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

Product name/Product size	NDC Number	Product Code	Batch Number	Expiration Date	First Ship Date	Last Ship Date
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	460137	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

Fresenius **Kabi** USA LLC is 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.