Pharmacy_Subscriberlist@DCA

From: Board of Pharmacy <pharmacy.subscriberlist@DCA.CA.GOV>
Sent: Tuesday, April 26, 2016 3:29 PM
To: PHARM-GENERAL@DCALISTS.CA.GOV
Cc: Pharmacy_Subscriberlist@DCA
Subject: Sensorcaine-MPF (bupivacaine HCl) by Fresenius Kabi: Recall - Presence of Particulate Matter

AUDIENCE: Surgery, Dentistry, OBGYN, Nursing, Pharmacy

ISSUE: Fresenius Kabi USA announced today it is voluntarily recalling a single lot (Lot Number 6111504; Product Code 470237) of Sensorcaine®-MPF (bupivacaine HCl) Injection, USP, 0.75%, 7.5 mg/mL, 30 mL fill in a 30 mL vial. The recall is being performed to the user level due to visible particulate matter characterized as glass observed by the company during inspection of reserve samples. Administration of a solution containing glass particulate matter by the epidural or retrobulbar (behind the eyeball) route may result in inflammation and injury, or cause blockage of vasculature around the eye or emboli in the vasculature of eye nerves. If the particulate goes undetected and solution is administered - depending on the particle size and number - it could block administration of the drug to the patient, causing a delay in therapy. If the particulates are able to pass through the catheter and may result in local inflammation, mechanical disruption of tissue or immune response to the particulate. To date, Fresenius Kabi has not received any reports of adverse events related to this recall.

BACKGROUND: Sensorcaine®-MPF (bupivacaine HCl) Injection is indicated for the production of local or regional anesthesia or analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures and for obstetrical procedures. The recalled product is labeled with Product Code 470237 and Lot Number 6111504 and is supplied as 0.75% strength in a 30 mL single dose flint molded vial and packaged in units of 25. The product was shipped in the United States to wholesaler and distributor outlets between March 4, 2016 and March 21, 2016 and has an expiration date of September 2019. The NDC number for this product is 63323-472-37.

RECOMMENDATION: Fresenius Kabi is notifying its distributors and customers by letter and is arranging for return of all recalled product. If health care facilities have the affected lot, they are to immediately discontinue distributing, dispensing or using the lot and return all units to Fresenius Kabi. Distributors are instructed to immediately notify their customers that have been shipped, or may have been shipped the product involved in this recall and direct them to discontinue distributing, dispensing or using the affected lot and return the product to Fresenius Kabi.

Consumers with questions regarding this recall can contact Fresenius Kabi at 1-800-551-7176 Monday through Friday, during the hours of 8:00 a.m. to 5:00 p.m. or productcomplaint.USA@fresenius-kabi.com or adverse.events.USA@fresenius-kabi.com. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this drug product.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

[04/25/2016 - Press Release - Fresenius Kabi]