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Visible particles, discolored solution prompt bupivacaine recall

Hospira, Inc. is recalling one lot of 0.25% Marcaine (bupivacaine HCl Injection, USP) after confirming a report of visible particles embedded in a glass vial as well as discolored solution.

The product is sold in preservative-free 10 mL, single-dose vials (NDC 0409-1559-10), and the recalled lot number is 34-440-DD.

If the particulate goes undetected and solution is administered, it could block administration of the drug to the patient, causing a delay in therapy. Other risks include local inflammation, mechanical disruption of tissue or immune response to the particulate, according to a Food and Drug Administration (FDA) MedWatch report.

Packaged 10 units per carton/100 units per case in glass fliptop vials, the product was distributed from December 2013 through January 2014 to wholesalers/distributors, hospitals and clinics nationwide.

Stop using the recalled solution and quarantine any existing inventory. In addition, Hospira is asking customers to inform potential users of this product in their organizations.

The firm will notify its direct distributors/customers via a recall letter and arrange for the product to be returned to Stericycle at 877-546-7642. For clinical questions about the Marcaine recall, call Hospira at 800-615-0187 (medical inquiries) or 1-800-441-4100 (report adverse events or product complaints).

Adverse reactions or problems experienced with the use of this product should be reported to the FDA at www.fda.gov/Safety/MedWatch/HowtoReport/default.htm or by calling 800-332-1088.

Read the MedWatch safety alert, including a link to the news release at: www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm394464.htm.