MedWatch The FDA Safety Information and Adverse Event Reporting Program

Lidocaine HCl Injection, USP, by Hospira: Recall - Visible Particulates

[Posted 04/18/2014]

AUDIENCE: Pharmacy, Patient, Health Professional, Nursing

ISSUE: Hospira, Inc. will initiate a voluntary recall of one lot of 1% Lidocaine HCl Injection, USP, 10mg/mL, 30 mL single dose, Preservative - Free to the user level due to a confirmed customer report of orange and black particulate within the solution and embedded within the glass vial. Hospira has identified the particulate as iron oxide. Risk factors associated with the particulate include the potential for particulate to be injected and/or a delay in therapy.

If the particulate or smaller pieces of the particulate that could break off, become free floating within the solution pass through the catheter into the patient, it may result in local inflammation, and/or mechanical disruption of tissue or immune response to the particulate. Chronically, following sequestration, local granuloma formulation may occur.

BACKGROUND: This lot (Lot # 31-427-DK, Expiration Date 1JUL2015) was distributed nationwide to distributors/wholesalers, hospitals and clinics from September 2013 through October 2013.

RECOMMENDATION: Anyone with existing inventory should immediately stop use and quarantine any affected product. In addition, customers should inform potential users of this product in their organizations of this notification. Hospira will be notifying its direct distributors/customers via a recall letter and will arrange for impacted product to be returned to Stericycle for returns processing. For additional assistance, call Stericycle at 1-888-835-2723. For medical inquiries, please contact Hospira Medical Communications at 1-800-615-0187.

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.htm
- 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

Read the MedWatch safety alert, including a link to the Press Release at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm394026.htm

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You are encouraged to report all serious adverse events and product quality problems to FDA MedWatch at www.fda.gov/medwatch/report.htm

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Lidocaine HCl Injection 2%, 5 ml Vial by Hospira: Recall - Presence of Particulate Matter

AUDIENCE: Risk Manager, Pharmacy, Anesthesiology

ISSUE: Hospira initiated a voluntary nationwide recall to the user level for one lot of Lidocaine HCl Injection, USP, 2%, 5 mL Single-Dose Vial (NDC 0409-2066-05), Lot 32-135-DD, expiration date 1AUG2015. The recall is due to a reddish orange particulate on the inner surface and floating in the solution.

If particulate goes undetected and solution is administered, the particle may potentially block the infusion of the solution to the patient, resulting in a delay in therapy. If smaller pieces of the particulate break off and become free floating within the solution, they may pass through the catheter into the patient, resulting in local inflammation or mechanical disruption of tissue. Chronically, following sequestration, local granuloma formulation is possible. In consideration of the reddish orange color of the particulate, if there is iron within the particle that is infused, it may put a patient at risk when undergoing MRI (strong magnetic field exposure), as the particle could potentially be dislodged and be pulled through tissue, causing local inflammation and tissue trauma.

BACKGROUND: The recalled lot was distributed to distributors/wholesalers, hospitals, and pharmacies located in AL, AZ, CA, CO, FL, GA, HI, IL, IN, KY, LA, MD, MA, MI, MS, MO, NV, NJ, NC, OH, OK, PA, TN, TX, UT, VA, WA, and WI between September 2013 through October 2013. Lidocaine is packaged 10 units per carton/180 units per case in single dose glass fliptop vials.

RECOMMENDATION: Anyone with an existing inventory should immediately stop use and quarantine any affected product and return the product to Stericycle. Hospira will be notifying its direct distributors/customers via a recall letter and will arrange for impacted product to be returned to Stericycle for returns processing. For additional assistance, call Stericycle at 1-855-695-8596 between 8 a.m. and 5 p.m., ET, Monday through Friday.

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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.

Read the MedWatch safety alert including links to the press release at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/

The FDA Safety Information and Adverse Event Reporting Program

Lidocaine HCl Injection, USP, 2 percent, by Hospira: Recall - Visible Particulates

AUDIENCE: Pharmacy, Patient, Health Professional, Nursing

ISSUE: Hospira, Inc. is recalling one lot of Lidocaine HCl Injection, USP, 2%, 20 mg per mL, 5 mL single-Dose Vial, Preservative-Free (NDC 0409-2066-05; Lot 25-550-DD, Expiry 1JAN2015) to the user level due to a confirmed customer report of discolored product with visible particles in the solution as well as particulate embedded in the molded glass container. Hospira has identified the particulate as iron oxide.

Risk factors associated with the particulate include the potential for particulate to be injected and/or a delay in therapy. 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. Particulates may be able to pass through the catheter and may result in local inflammation, mechanical disruption of tissue or immune response to the particulate. While extremely rare, particulate exposed to strong magnetic fields (e.g. MRI), could potentially dislodge and cause tissue damage.

BACKGROUND: Lidocaine is packaged 10 units per carton / 180 units per case in single-dose glass fliptop vials. This lot was distributed nationwide to distributors/wholesalers, hospitals and clinics from June 2013 through July 2013.

RECOMMENDATION: Anyone with existing inventory should immediately stop use and quarantine any affected product. In addition, customers should inform potential users of this product in their organizations of this notification. Hospira is notifying its direct distributors/customers via a recall letter and will arrange for impacted product to be returned to Stericycle for return processing. For additional assistance, call Stericycle at1-855-827-6586 (M-F, 8 a.m. - 5 p.m. ET). For clinical inquiries, refer to the Firm Press Release.

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- 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

Read the MedWatch safety alert, including a link to the press release, at:

http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm407249.htm

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