Lactated Ringer's Irrigation, 3000mL by Hospira: Recall - Mold Contamination

[Posted 03/12/2015]

AUDIENCE: Pharmacy, Risk Manager

ISSUE: Hospira initiated a voluntary recall of one lot of Lactated Ringer's Irrigation, 3000mL (NDC 0409-7828-08, Lot 40-008-JT; Expiry 1APR2016) to the user level (both human and veterinary) due to a confirmed customer report of several dark, fibrous particulates floating within the solution of the primary container. The particulate was confirmed as a common non-toxic, non-invasive mold, Aspergillus kanagawaensis.

If contaminated solution is used on a patient it may cause bacteremia, sepsis, septic shock and endocarditis, and death may result. Signs and symptoms may include redness, pain, swelling at the site, fever, shortness of breath, tachycardia, nausea, and vomiting. Septicemia could lead to shock and multi-system organ failure, requiring critical medical intervention. The mold is considered allergenic and exposure to it may induce an allergic response or immune response to the particulate including anaphylaxis. Delayed therapy may occur if the particulate were to block the flow of the solution during irrigation.

BACKGROUND: Lactated Ringers Irrigation is a sterile, nonpyrogenic solution of electrolytes in water for injection, intended only for sterile irrigation, washing and rinsing purposes. The product is packaged in 3000 mL flexible container bags and sold four bags per carton (NDC: 0409-7828-08, Lot 40-008-JT, Expiry 1APR2016). The lot was distributed nationwide in the United States to wholesalers, distributors, surgery centers, and hospitals from June 2014 through September 2014. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

RECOMMENDATION: Anyone with an existing inventory of the recalled lot should stop use and distribution, and quarantine the product immediately. Customers should notify all users in their facility. Customers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product and instruct them if they have redistributed the product to notify

their accounts, locations or facilities to the user level (both human and veterinary). Hospira will be notifying its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. For additional assistance, call Stericycle at 1-877-907-7037 between the hours of 8 am to 5 pm ET, Monday through Friday.

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

[03/11/2015 - Press Release - Hospira]

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