FDA MedWatch - Dobutamine Injection (250mg/20mL)/Hospira: Recall - Visible Particulates

05/15/2014

AUDIENCE: Risk Manager, Pharmacy, Cardiology, Anesthesiology, Emergency Medicine

ISSUE: Hospira, Inc. issued a nationwide recall to the user level for one lot of Dobutamine Injection, USP, 250 mg, 20 mL, Single-dose fliptop vial, (NDC 0409-2344-02), Lot 27-352-DK. (NDC and lot number can be found on the right-hand side of the primary label). This lot was distributed nationwide to distributors/wholesalers, hospitals and clinics from August 2013 through September 2013.

Risk factors associated with particulate and/or a glass defect include the potential for particulate to be injected, a breach of sterility/contamination of the vial contents, leakage of contents, and/or a delay in therapy. In general, injected particulate matter may result acutely in local inflammation, phlebitis, and/or low level allergic response through mechanical disruption of tissue or immune response to the particulate. If contaminated solution is used on a patient, this may potentially cause bacteremia, sepsis, septic shock and endocarditis, and death may result. Leakage may result in drug wastage, spillage onto equipment, flooring and personnel. If a defective vial is not detected until the point of care, there may be a delay in therapy.

BACKGROUND: The recall was due to a confirmed customer report of discolored solution. Upon review of the complaint, a chip in the glass at the neck of the vial was identified as well as glass particulate within the solution. To date, Hospira has not received reports of any adverse events associated with this issue for this lot.

RECOMMENDATION: Anyone with an 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. Dobutamine should be considered a potent drug and potentially irritating to eyes and respiratory tract. Users should avoid liquid aerosol generation and skin contact.

For additional assistance, call Stericycle at 1-877-907-9956 (M-F, 8 a.m - 5 p.m. ET).

For medical inquiries, please contact Hospira Medical Communications at 1-800-615-0187. This phone number is available 24 hours a day, seven days a week.

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/ucm397449.htm