U.S. Food and Drug Administration
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Company Announcement

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

Hospira Issues a Voluntary Nationwide Recall For One Lot Of 0.25% Bupivacaine Hydrochloride Injection, USP Due to The Presence Of Particulate Matter Within a Single Vial

For Immediate Release

August 5, 2016

Contact

Consumers

Hospira
888-345-4680

Media

Hospira
610-329-1340

Announcement

Lake Forest, IL - Hospira, Inc., a Pfizer company, is voluntarily recalling one lot of 0.25% Bupivacaine Hydrochloride Injection, USP (NDC: 0409-1159-02, Lot 59-064- DK, Expiry 1NOV2017) at the hospital/retail level due to the presence of particulate matter within a single vial. The issue was identified through a confirmed complaint.

In the event that the particulate is administered to a patient, it may result in local swelling, irritation of bloodvessels or tissue, blockage of blood vessels and/or low-level allergic response to the particulate. The risk is reduced by the possibility of detection, as the label contains a clear statement directing the physician to visually inspect the product for

particulate matter and discoloration prior to administration.

To date, Hospira has not received reports of any adverse events associated with this issue for this lot. Hospira places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process.

0.25% Bupivacaine Hydrochloride Injection, USP is indicated for the production of local or regional anesthesiaor analgesia for surgery, dental and oral surgery procedures, diagnostic and therapeutic procedures, and for obstetrical procedures.

The product is packaged 50 units of 30 mL Single-use Teartop Vials per case, (25 Bottles per tray, two trays per case). The lot was distributed nationwide in the U.S. to wholesalers and hospitals between December 2015 and January 2016. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Anyone with an existing inventory of the recalled lot should stop use and distribution and quarantine the product immediately. Inform Healthcare Professionals in your organization of this recall. If you have further distributed the recalled product, please notify any accounts or additional locations which may have received the recalled product from you. Further, please instruct entities that may have received the recalled product from you that if they redistributed the product, they should notify their accounts, locations or facilities of the recall to the hospital/retail level. 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 1-888-570-1678 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday. Reference Stericycle Event number 6059.

For clinical inquiries, please contact Hospira using the information provided below.

Hospira Contact	Contact Information	Areas of Support
Hospira Global Complaint Management	1-800-441-4100 (9am-6pm ET, M-F)	To report adverse events or product complaints
Hospira Medical Communications	1-800-615-0187 (Available 24 hours a day/7 days per week)	Medical inquiries

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

· Complete and submit the report Online: **www.fda.gov/medwatch/report.htm (http://www.fda.gov/MedWatch/report.htm)**
· Regular Mail or Fax: Download form **www.fda.gov/MedWatch/getforms.htm (http://www.fda.gov/MedWatch/getforms.htm)**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

This recall is being executed with the knowledge of the U.S. Food and Drug Administration.

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