Hospira Issues Voluntary Worldwide Recall For Lots of Hydromorphone HCl Injection, USP, CII, (2 mg/mL) 1mg Vial, and Levophed® (Norepinephrine Bitartrate Injection, USP), 4 mg/4 mL (1 mg/mL) Vial, Due to a Lack of Sterility Assurance

Consumers Contact: 1-888-345-4680
Media Contact: 610-329-1340

For Immediate Release-LAKE FOREST, Ill., September 12, 2017 - Hospira, Inc., a Pfizer company, is voluntarily recalling one lot of Hydromorphone HCI Injection, USP, CII (2 mg/mL) 1mg Vial and four lots of Levophed® (Norepinephrine Bitartrate Injection, USP), 4 mg/4 mL (1 mg/mL) Vial due to a potential lack of sterility assurance resulting from use of a damaged sterilizing filter for nitrogen used in the manufacturing process. To date, Hospira, Inc., a Pfizer company has not received any reports of adverse events related to this recall.

In the event that impacted product is administered to a patient, adverse events ranging from fever, chills, and malaise, to severe adverse events such as septicemia, bacterial meningitides and wound infection could occur. The possibility of a breach in sterility assurance in distributed product, while not confirmed, cannot be eliminated. No batches of product have been identified as containing microorganisms. To date, Hospira has not received reports of any adverse events associated with this issue for these lots. Hospira places the utmost emphasis on patient safety

and product quality at every step in the manufacturing and supply chain process.

Hydromorphone Hydrochloride Injection, USP, CII is indicated for the relief of moderate to severe pain. Levophed® (Norepinephrine Bitartrate Injection, USP) is indicated in adults for blood pressure control in certain acute hypotensive states.

The following lots were distributed Nationwide in the U.S.A (including Puerto Rico), Singapore, and Taiwan to wholesalers and hospitals from May 2017 to July 2017. Hospira has initiated an investigation to determine the root cause and corrective and preventive actions.

Product/Lot Information (for US/Puerto Rico lots)

Product	NDC	Lot Number	Expiration Date	Strength	Configuration/Count
HYDROmorphone HCl Injection, USP CII	Carton: 0409-3365-01 Vial: 0409-3365-11	760853A	1APR2019	2 mg/mL, 1 mL in 2 mL Vial	25 Vials per Carton; 20 Cartons per Case
Levophed® (norepinephrine bitartrate injection, USP)	0409-3375-04	753003A	1SEP2018	1 mg base/mL, 4 mL in 5 mL Vial	10 Vials per Carton; 18 Cartons per Case
Levophed® (norepinephrine bitartrate injection, USP)	0409-3375-04	762153A	1OCT2018	1 mg base/mL, 4 mL in 5 mL Vial	10 Vials per Carton; 18 Cartons per Case
Levophed® (norepinephrine bitartrate injection, USP)	0409-3375-04	760803A	1OCT2018	1 mg base/mL, 4 mL in 5 mL Vial	10 Vials per Carton; 18 Cartons per Case

Product/Lot Information (for Singapore and Taiwan lot)

Levophed® (norepinephrine bitartrate injection, USP)	761053A	1OCT2018	1 mg base/mL, 4 mL in 5 mL Vial	10 Vials per Carton; 18 Cartons per Case

Anyone with an existing inventory of the recalled lots should stop use and distribution and quarantine 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 level.

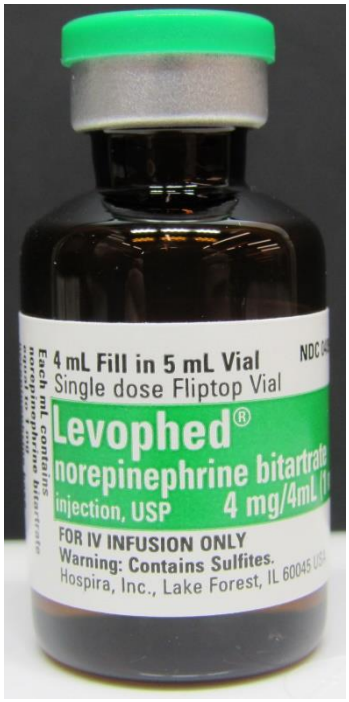
Hospira has notified its direct customers via a recall letter and is arranging for impacted product to be returned to Stericycle in the United States. For additional assistance, call Stericycle at 1-800-805-3093 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.
For clinical inquiries, please contact Hospira using the information provided below.

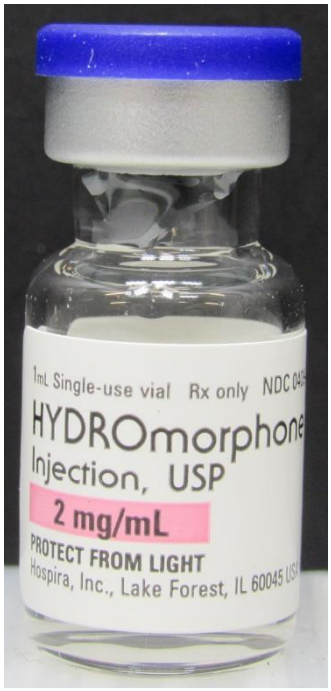
Hospira Contact	**Contact Information**	**Areas of Support**
Pfizer Complaint Management	1-800-438-1985 (24 hours a day 7 days per week)	To report adverse events or product complaints
Pfizer Medical Information	1-800-615-0187 (8am to 7pm ET Monday through Friday)	Medical inquiries

Adverse reactions or quality problems experienced with the use of these products 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**
- **Regular Mail or Fax:** Download form **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.


4 mL Fill in 5 mL Vial
Single dose Fliptop Vial
Levophed®
norepinephrine bitartrate
injection, USP
FOR IV INFUSION ONLY
Warning: Contains Sulfites.
Hospira, Inc., Lake Forest, IL 60045


1mL Single-use vial Rx only
HYDROmorphone
Injection, USP
2 mg/mL
PROTECT FROM LIGHT
Hospira, Inc., Lake Forest, IL 60045

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