

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

For Immediate Release

August 31, 2017

Contact

Consumers

☎ 1-888-345-4680

Media

☎ 610-329-1340

Announcement

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Hospira, Inc., a Pfizer company, is voluntarily recalling one lot of Hydromorphone HCl Injection, USP, CII (2 mg/mL) 1mg/mL 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 (<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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