Company Announcement

Hospira Issues a Voluntary Nationwide Recall for Hydromorphone HCL Injection, USP CII Due to The Potential for Empty or Cracked Glass Vials

For Immediate Release

March 5, 2018

Contact

Consumers

Stericycle
1-800-805-3093

Media

610-329-1340

Announcement

View Product Photos

Hospira, Inc., a Pfizer company, is voluntarily recalling three lots of Hydromorphone HCl Injection, USP CII 10 mg/mL, 1 mL in 2 mL Single Dose Vials lot numbers 71330DD (NDC 0409-2634-01), and 691853F and 700753F (NDC 0703-0110-01 – Teva lots) to the hospital/institution level. Hospira, Inc. initiated this recall on February 07, 2018 due to the potential that units from these lots may be empty or cracked at the bottom of the glass vial.

Cracked vials may compromise the sterility of the product. Use of or exposure to cracked units may be associated with adverse events such as sharps injury to healthcare professionals. Intravenous infusion of a non-sterile solution can lead to bloodstream infections, which may potentially lead to bacteremia or sepsis. These infections are of concern especially to immunocompromised patients. To date, Hospira, Inc. has not received reports of any adverse events associated with this issue for these lots.

Hydromorphone HCl is an opioid agonist indicated for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate. It is also indicated for use in opioid-tolerant patients who require higher doses of opioids for the management of pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate.

Hydromorphone HCl Injection, USP CII 10 mg/mL, 1 mL in 2 mL Single Dose Vials, is packaged in a carton of 10 x 1 mL Single- dose vials. The affected lots include the following NDC, lot numbers and expiry dates. Product was distributed nationwide to wholesalers/distributors/retailers/hospitals in the United States and Puerto Rico from October 2016 to July 2017.

Product Name	NDC	Lot Number	Expiration Date	Strength	Configuration/Count
Hydromorphone Hydrochloride Injection, USP - CII High Potency Formulation	0409-2634-01	71330DD (Distributed by Hospira to U.S.)	1NOV2018	10 mg/mL	Carton of 10 x 1 mL Single-dose Vials
Hydromorphone Hydrochloride Injection, USP - CII High Potency Formulation	Vial NDC: 0703-0110-01 Carton NDC: 0703-0110-03	691853F 700753F (Note: **Distributed by Teva to U.S.1**)	1SEP2018 1OCT2018	10 mg/mL	Carton of 10 x 1 mL Single-dose Vials

Note 1: Teva Parenteral Medicines, Inc. is already conducting a sub-recall for the two lots indicated above.

Hospira, Inc. places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process. Hospira, Inc. has notified wholesalers/ distributors/retailers/hospitals by recall letter to arrange for return of any recalled product.

Wholesalers/distributors/retailers/hospitals with an existing inventory of the lots subject to this recall should stop use and distribution of the remaining units and quarantine immediately. Healthcare Professionals in your organization should be informed of this recall. If you have further distributed the recalled product, to the wholesale or retail level, please notify any accounts or additional locations which may have received the recalled product from you. 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.

Retailers/Healthcare Professionals with questions regarding this recall can contact Pfizer using the below information.

Contact	Contact Information	Areas of Support
Pfizer Medical Information	1- 800-615-0187, option 3 (8 am to 7 pm ET Monday through Friday)	Medical inquiries

Contact	Contact Information	Areas of Support
Pfizer Safety	1-800-438-1985, option 1 (24 hours a day 7 days per week)	To report adverse events or product complaints

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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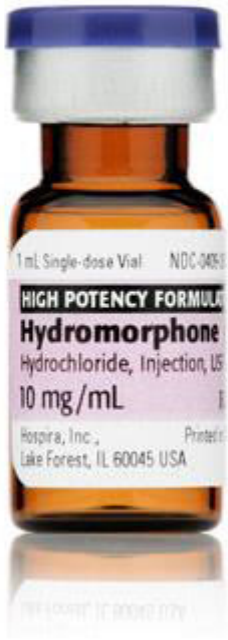
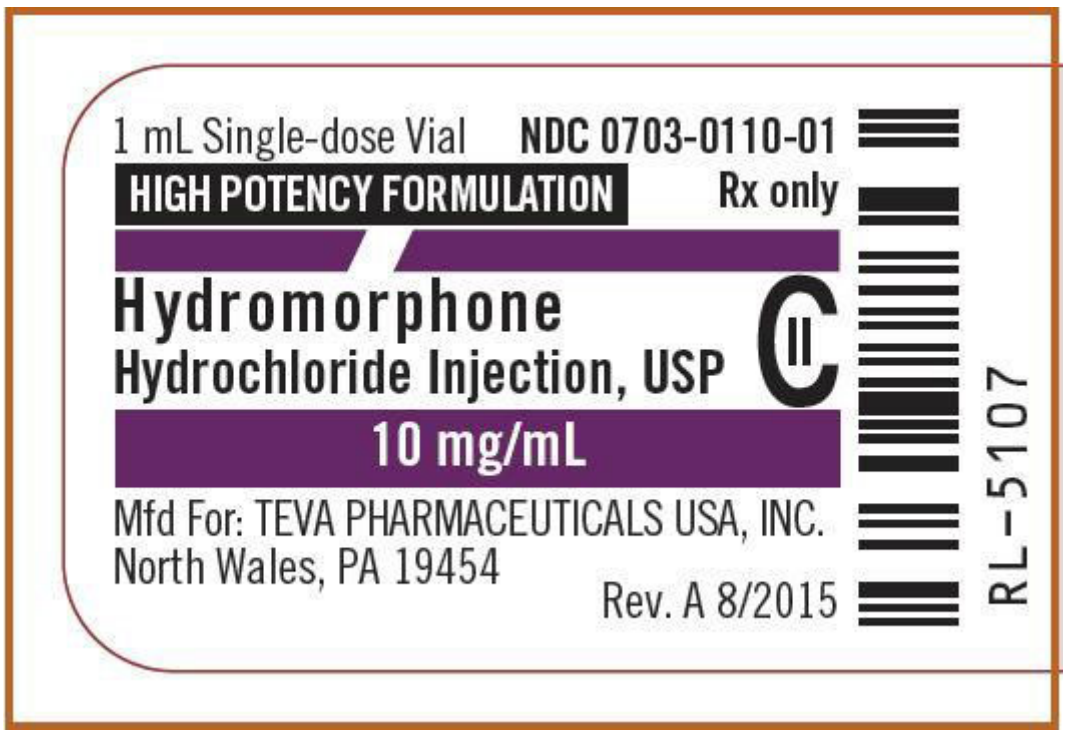
Product Photos





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